EXHIBIT L

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
CASE NO. 291 CT
MASTER CASE NO. L-6341-10

- - -

IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

VOLUME I
Thursday, November 15, 2012

- - -

Oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 9:56 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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Reserved for Confidential Designation Index as Pursuant to the Protective Order

Defendants did not have any Confidential Designations.

Reserved for Confidential Designation Index as Pursuant to the Protective Order

(Exhibit Elliott-1 was marked for identification.)

DANIEL STEVEN ELLIOTT, M.D., having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SNELL:

Q. Good morning, Doctor.

A. Good morning.

Q. My name is Burt Snell, and I'm here to take your deposition in the litigation involving Ethicon surgical meshes for prolapse and urinary incontinence.

Have you ever given a deposition before?

A. Yes.

Q. On how many occasions?

A. A rough estimate would be about 15.

Q. So I'll give you a quick, abbreviated instructions list. You know all these things.

You're here under oath, just like if you were at trial; correct?

A. Correct.

Q. You need to answer all my questions verbally. Shaking or nodding of the head does not translate into the record. Try to avoid saying unh-unh or uh-huh because those do get jumbled.

If you can wait for my question to end before you answer and I'll do my best not to speak over you before you're finished answering, that way we get a clean record. Sometimes you'll probably know where I'm going and you'll be ready to answer but just let me finish my question so we can get a clear transcript.

Is that okay?

A. Sure.

Q. If you don't understand one of my questions, please feel free to tell me, ask me to rephrase it or repeat it. I don't profess to be a physician, I'm not a doctor, so sometimes I might mix up terminology. It's okay to correct me or tell me, you know, that you'd like me to rephrase it or if you can answer it as best you can if you think you understand it, just feel free to do so.

Do you have any questions before we begin?

A. No.

Q. When was the first time you gave a deposition?

A. I won't be able to tell you an exact date. It probably would have been -- because I've been on staff at Mayo since 2000. It would have been a year or two after that, probably. That's a very rough estimate.

Q. Your best approximation is somewhere around 2002?

A. That's a fair estimate.

Q. Have you ever given testimony at trial?

A. Yes.

Q. On how many occasions?

A. Once.

Q. Where was that trial at?

A. Tacoma, Washington. The district courthouse there, I believe.

Q. What type of case was it?

A. Patent infringement.

Q. Besides today, when was the last

time you gave a deposition?

A. I believe June, maybe May, of this year, 2012.

Q. Have you ever testified in a case as an expert witness?

A. Yes.

Q. On how many occasions?

A. Once.

Q. The 15 depositions that you have given, was one of those your testimony as an expert witness?

A. No. Oh, wait. Excuse me. Yes, that would have probably been included in there because I'm giving you a rough estimate. So, yes, that would have included that.

Q. What were the other approximate 14 cases about that you gave deposition testimony in?

A. They were patients that I took care of at Mayo that were being -- the outside physician was being sued. So it was pertaining to my medical care at Mayo, from the first day that I saw them to the last day that I saw them.

Q. So these depositions involved your role as a treating physician for the patient?

A. Correct. Yes. I was not the one being sued.

Q. Have you ever been sued?

A. No.

Q. And all of these patients were patients whom you had seen at Mayo Clinic?

A. Correct.

Q. Were all of these patients seen after your medical schooling and training through fellowship?

A. Correct.

Q. So it was after your training time.

A. My fellowship finished June 30th of 2000, so all this took place after -- when I was on staff.

Q. Did any of the depositions that you gave as a treating physician involve the use of a medical device?

A. Yes.

Q. Which ones?

A. They were meshes. The roughly --

I'm only going to give you a rough estimate. The first six, seven depositions were all involving non-medical devices, surgical issues, and then the last seven or so -- again, that's a rough estimate -- were all pertaining to meshes for transvaginal use.

Q. Can you tell me the names of the patients or the case names of these meshes -- sorry -- of the cases that involved transvaginal mesh?

A. I don't understand your question. You changed it. What are you asking?

Q. Can you tell me the names of the patients, the plaintiffs, in these cases where you've testified as a treater where the case involved transvaginal mesh use?

A. Well, for confidentiality purposes, I can't be giving you patient names. Number one, I won't be able to remember them. But if I could remember them, I can't give you their names.

Q. You can give the names. If you were testifying in a litigation, in a deposition, that's public.

A. Okay. Then I -- well, I can't

remember them. I can't recall them. Even the one in June I can't recall. I remember some issues pertaining to the case but not the patient name.

Q. Can you tell me the issues you recall pertaining to the case?

A. Most specifically, the one in May or June was a transvaginal mesh for prolapse. I don't recall which company product it was. The woman had it placed in Atlanta, I do know that, and she had complications.

Q. What type of complications?

A. Pelvic pain, dyspareunia, voiding dysfunction, ambulatory difficulties. Off the top of my head, that's fairly thorough.

Q. Do you recall the name of the physician involved or any of the physicians?

A. Excuse me. No, I do not.

Q. Do you recall the name of the lawyers who took your deposition?

A. They were based in Atlanta so I don't -- I'm not familiar.

Q. Did anyone represent you at that deposition?

A. Well, no one -- I mean, Mayo has their team of 30 or 40 lawyers. So no one was in the room with me representing me. I had access to the Mayo legal team if I asked for it, but I didn't ask for it. So I don't know if that answers your question or not.

Q. No. That does.

Can you tell me the details of any of the other cases in which you gave testimony as a treating physician that involved mesh use or mesh used transvaginally?

A. I won't be able to give you specifics just because I don't recall.

There are various different with anti-incontinence procedures, bladder perforations, urethral perforations, pain. And then with the meshes for transvaginal purposes it would be, again, somewhat similar, though usually it was pain, pelvic pain or dyspareunia. But I must emphasize, that's a rough estimate because I just don't recall.

Q. You don't have a good recollection.

A. No, I do not.

Q. Do you have a recollection, then, as to whether any of these were Prolifts® which you gave testimony on as a treating doctor?

A. I don't recall. All I can remember, again, just the most recent one was in May or June and that was not. That was Avaulta, I believe.

Q. Avaulta.

A. Again, just to emphasize, that is a guess. I believe that's what it was.

Q. As you sit here today, your best recollection is it was Avaulta?

A. Correct.

Q. Were any of the mesh products for which you gave testimony as a treater that involved transvaginal placement, did they involve the Prosima® product?

A. I don't recall.

Q. Did any of these cases involving the transvaginal mesh for which you gave testimony as a treating physician involve the Prolift® M?

A. I don't recall.

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Q. Plus M?
A. I don't recall.
Q. Have you ever given testimony as a treating physician in a case that involved TVT®?
A. Yes.
Q. On how many occasions?
A. Again, I'm going to have to only give you a rough estimate. It was probably one or two times. There's definitely once but, again, beyond that, I can't really accurately recall.
Q. When was the first TVT® case that you gave testimony in?
A. I don't recall. It would have been probably in the three or four or five years ago time range.
Q. Were you also testifying in that case as a treating physician?
A. Yeah. I -- I was not the one who put the product in. I was the one who took care of the problem afterwards. So yes, it was the -- my care -- it was specifically my care from the first day she showed up in the office until the last day I saw her.

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Q. And where was that case situated at? Do you recall?
MR. ANDERSON: The TVT®?
MR. SNELL: Yes.
THE WITNESS: Where the TVT® was placed?
BY MR. SNELL:
Q. Where was the TVT® case situated, filed? Was it a Minnesota case or somewhere else?
A. Oh. I have no idea. Because Mayo gets people from all over the world, so all 50 states, so I don't -- I don't recall.
Again, the only reason I remember the one in -- the last one, the mesh case in June, was because it was a recent one and I had just been in Atlanta for another meeting so it's kind of stuck in my mind.
Q. The TVT® case that you gave testimony in, the first one, did it involve the retropubic or transobturator product?
A. No. It was the -- yeah, the retropubic approach.
Q. Do you recall the name of the

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plaintiff's counsel or the defense lawyer there?
A. No, I do not.
Q. Were you represented in that matter, in that case?
A. Same answer as before. To the best of my knowledge, only one time I've had the Mayo lawyer team in the room with me, and that was not pertaining to a mesh. So Mayo legal team represents me but, again, they were not in the room.
Q. Can you tell me the case where you had the Mayo Clinic legal in the room with you?
A. It was my first or second deposition and it was a rectourethral fistula following -- for prostate cancer, brachytherapy seeds, and a hole developed between the rectum and the prostate.
Q. And how did it develop?
A. As a result of radiation therapy for brachytherapy.
Q. And this was radio -- radiation or radiotherapy?
A. Radiation, yeah.

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Radiation can be given either external beam or with seed implants for prostate cancer. Seed implants, another term for that is brachytherapy. And then the hole developed following that.
Q. And this was brachytherapy given by some other physician and not you?
A. Correct. I did not give it. Yeah.
Q. What do you recall about the TVT® retropubic case in which you gave testimony in as a treating physician?
A. The one that I can remember in particular, it was a bladder perforation.
Q. Was the bladder perforation recognized at the time of surgery?
A. No, it was not. Specifically, I can tell you there was a cystoscopy note said there was no perforation.
Q. What did your course of care consist of in that matter in which you gave deposition testimony upon?
A. Briefly, the patient came to see me for recurrent urinary tract infections, irritative voiding symptoms, burning with

urination and pelvic pain.
We performed a physical exam, which, as I recall, was negative, performed a cystoscopic exam, which showed two meshes going through bilaterally in the bladder or one on each side of the bladder.
Q. Do you know who placed that mesh?
A. It was an outside physician. I don't recall who it was.
Q. In any of the 15 cases where you gave deposition testimony in as a treating physician did you opine that another physician breached the standard of care in any manner?
A. Again, it's going to be difficult to recall each one in particular.
From my recollection, no, because specifically I was to offer an opinion specifically from the day they showed up at my office to the day they left. So I was instructed by the legal team not to offer an opinion --
Q. I don't want you to tell me what your legal team instructed you.
MR. ANDERSON: Listen to the

question and answer his question.
THE WITNESS: Okay.
BY MR. SNELL:
Q. Now, you said that there was -- you testified in TVT® cases one or two times and we talked about the TVT® retropubic case.
Can you tell me, what was the sum of your testimony in that TVT® retropubic case beyond, you know, the patient came to you as you testified --
A. Uh-huh.
Q. -- you know, you did a workup and you found mesh?
What else, if anything, did you testify to in that matter?
A. They asked how did I treat the situation, which that was at that point in time an open surgical repair. We went through the abdomen and took out the mesh.
They wanted to know what was the end result of it, if it cured the problem that she presented with, which, as I recall, the answer was yes.
And then, again, as far as I

recall, the discussion ended at that point in time. I'm sure there were other questions. I don't recall them, though.
Q. Who removed the mesh in that case?
A. I did. And my surgical team. It wasn't just me.
Q. Did you remove the entire mesh or just the portion that was in the bladder?
A. We removed -- that's an excellent question because that pertains to overall care and recurrence.
We removed from the -- everything we get from beneath the skin through the rectus, through the fascia, into the bladder, and then deep down into the pelvis to the level of the endopelvic fascia. As I recall, we did not perforate the endopelvic fascia and remove the suburethral portion.
Q. The other TVT® case that you gave testimony in as a treater, what type of TVT® product was that?
A. It was a retropubic also.
Q. And for the first TVT® case that

we were discussing, where did you physically sit when you gave that deposition testimony?
A. At the Mayo Clinic in the legal office.
Q. In the second TVT® retropubic case where did you physically give deposition testimony from?
A. Same place. All my depositions except for the patent infringement have been in the legal office at Mayo.
Q. And do you remember the names of the attorneys in the second TVT® retropubic case?
A. No, I do not.
Q. Do you remember approximately when you gave that deposition?
A. Again, it would have been -- no. To answer your question, no, I can't. I mean, I can give you a five-year time frame.
Q. The first TVT® retropubic case that we've discussed, was that the first one chronologically that you gave testimony in?
A. That's the first one that I can remember.
Q. That's fine.

And then now this second one we were talking about is sometime after that?
A. I don't -- I don't recall the dates.
Q. Okay.
A. I just happen to remember the bladder perforation most notably.
Q. Now, the second TVT® retropubic case, can you tell me the sum and substance of your testimony in that case?
A. I don't -- I -- on that one I do not remember any specifics.
Q. Earlier you testified that the last seven or so cases you gave deposition testimony in involving transvaginal mesh -- strike that.
You testified there were seven or so depositions you gave pertaining to transvaginal mesh use; correct?
A. Correct.
Q. And of those seven or so, two of them were TVT®.
A. That's a rough estimate. Yes.
Q. That's fine.
One may have been Avaulta,

which is the most recent one; correct?
A. Can you go back? Your question, then, so I make sure I understand, as I can recall --
Q. How about this? Let me withdraw it.
Of the seven cases that you gave deposition testimony in involving the transvaginal use of mesh, tell me the products that were involved.
A. Okay. I -- the only ones I'll be able to specifically tell you would be TVT® and then Avaulta. I do not recall all the others.
Q. As you sit here today, we've discussed two TVT® cases; correct?
A. Correct.
Q. Are those the only two that you recall?
A. That I recall, yes.
Q. And as you sit here today, we've discussed one case that was this year, I believe you testified in May or June.
A. Correct.
Q. And that you believe involved

Avaulta.
A. Correct.
Q. Are there any other Avaulta cases that you recall?
A. Not that I can recall, no.
Q. For any of the other seven cases that involved the use of transvaginal mesh do you recall the names of any of those patients?
A. No.
Q. Do you recall the names of any of the lawyers?
A. No. I could only give you the location that the last one was. They were based in Atlanta. That's all I remember.
Q. And do you know where any of those lawsuits were filed?
A. Just the one in Atlanta. I don't know if a case was filed, I have no knowledge of that, but all -- I was giving a deposition.
Q. And do you have the deposition transcripts from any of these depositions?
A. No, I do not.
Q. Does the Mayo Clinic have these

transcripts?
A. I would assume they would.
Q. Have you ever testified in Federal Court?
A. I don't know what that -- the case in Tacoma, that was a district court. I don't know the hierarchy of courts.
Q. Tell me about the case in Tacoma.
What was your role giving testimony there?
A. It was a patent infringement case, Coloplast versus GMD, which was Generic Medical Devices. And my role was with Coloplast as far as my opinion, whether the GMD product infringed upon the transobturator approach that is owned by Coloplast, I assume.
Q. You testified for Coloplast in that patent infringement matter?
A. Correct.
Q. Were you hired as an expert witness --
A. Yes.
Q. -- in that matter?
A. Excuse me. Yes.

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Q. And what was your expert opinion in that Coloplast matter with regard to the transobturator approach?
A. That the use of the GMD transobturator trochars and mesh infringed upon the Coloplast-held patent.
Q. And when did you give this deposition testimony in the patent infringement case for Coloplast?
A. The deposition was given in November of 2011.
Q. When were you retained as an expert?
A. The summer of 2009.
Q. And I believe you earlier testified that you also testified at trial in that case as well.
A. Correct.
Q. Was that a jury trial or a judge?
A. Jury.
Q. Did you issue any opinions about -- strike that.
In this patent infringement case that you gave deposition testimony in for Coloplast am I correct that it involved

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the transobturator use of synthetic mesh?
A. It would have been specifically the transobturator surgical approach. There was -- the mesh itself was not a part of -- as far as I recall, not a part of the patent. It was the surgical approach, the transobturator, that Coloplast owned. So it was not inclusive or exclusive of a mesh being used.
Q. And besides the synthetic mesh, can you tell me what other mesh material, cadaveric, autologous or whatever, is placed through a transobturator approach?
And I assume this is for -- let me back up. This -- I assume this is for stress urinary incontinence, this patent infringement?
A. Correct.
Q. So for stress urinary incontinence can you tell me what other material besides the synthetic mesh is placed via the transobturator approach?
A. As far as I know, only synthetic meshes are. But that was not what the patent was involving.

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Q. And you've used synthetic meshes in placing -- strike that.
You've used synthetic meshes in the past to treat stress urinary incontinence via the transobturator route; correct?
A. Correct.
Q. Did you give any opinions in this patent infringement case about the condition of stress urinary incontinence and whether it needed to be treated?
A. I gave as far as my expert report a description of stress urinary incontinence. But, again, the patent was not pertaining to what is being treated. The patent was the transobturator approach using those products.
Q. And the transobturator approach to treat stress urinary incontinence; correct?
A. Again, specifically, the patent was the transobturator surgery. That's what was being discussed. And if the GMD product was infringing upon that patent.
Q. Did you give any opinions about

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whether the transobturator surgery was a safe procedure?
A. Yes.
Q. What did you testify in that regard?
A. I felt when it was done correctly, it was a safe procedure.
Q. Did you give testimony about the efficacy of the transobturator surgery to treat stress urinary incontinence versus other surgical options?
A. I don't recall that question ever coming up or me offering an opinion.
Q. You didn't put that in your report?
A. I don't recall that specifically, no.
Q. You mentioned you issued a report in that patent infringement case.
Did you issue your report before your deposition testimony?
A. Yes.
Q. How many times were you deposed in that patent infringement case?
A. Once.

Q. And you gave trial testimony on one occasion.
A. Correct. Over two days, but yeah, one trial.
Q. Did the General Medical Devices, the party, have an expert opposite you?
A. Yes.
Q. What was his or her name?
A. Dr. George Webster.
Q. Before being involved in that case, did you know Dr. George Webster?
A. Yes.
Q. How did you know Dr. Webster?
A. Through meetings.
Q. What type of physician is Dr. Webster?
A. Urologist.
Q. Where does he practice?
A. Duke.
Q. Are you still retained in the patent infringement case?
A. No, I'm not.
Q. Do you have a list of testimony that you've given?
A. I don't understand the question.

Q. Do you have a document, a list of testimony, that you have given in the past?
A. I still don't understand it. A list of testimony? I don't --
Q. Do you have a document which contains a list of the prior depositions, trial testimonies --
A. Oh.
Q. -- you've given in the past?
A. No, I do not.
Q. You did not serve such a document with your expert report in the patent infringement case?
A. No. So I just want to clarify, you're asking do I have a list of all the depositions I've given? I mean, okay, no, I do not have that at all.
Q. A list of all the depositions you've given in any matter.
A. Yeah.
Q. Not just involving Mayo.
A. No. I have not given any depositions except being at Mayo. So during my training -- well, my training is Mayo. I did one year of fellowship at Baylor College

of Medicine at Houston. I did not give anything there.
Q. In any of the cases where you testified with regard to the use of transvaginal mesh did you testify that the use of mesh was improper in that case?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I'd have to clarify the question. Please rephrase it so I can understand.
BY MR. SNELL:
Q. In the seven or so cases you gave testimony pertaining to transvaginal use of mesh did you ever give deposition testimony that the use of mesh was improper?
A. To the best of my recollection, no. I was giving testimony pertaining to the complications that happened afterwards and specifically, no, I did not say they were improper.
Q. Did you give any deposition testimony in those seven or so cases involving transvaginal mesh that some other surgical procedure to treat the condition

should have been performed?
A. No. You -- I -- again, let me go back to clarify.
Q. Uh-huh.
A. Are you asking should a non-mesh procedure have been performed?
Q. Any other type of procedure.
A. Okay. No, I did not.
Q. For example, just to make sure we're on the same page, if it was a case involving the Avaulta product, that's a product to treat prolapse; correct?
A. Correct.
Q. In that case, did you give deposition testimony that some other surgical procedure should have been performed instead of Avaulta, such as sacrocolpopexy, colporrhaphy, any other prolapse surgery?
A. No, never. That was not my role. My role was dealing with the complications. So no, I did not give an opinion that way.
Q. So now that we're on the same page and, hopefully, we're understanding each other, just so I'm clear, in those

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seven cases involving transvaginal use of mesh did you give testimony that some other surgical procedure should have been performed instead of the particular procedure in a case?

A. Okay. To the best of my knowledge, no, never.

Q. The first six or seven depositions you gave involved surgical issues.

A. Correct.

Q. Can you tell me what they involved?

A. Most of them were rectourethral fistulas, like I mentioned earlier, from radiation damage.

There was one that I can recall, again, neurogenic bladder following a fall, an inability to work. And that's all I can recall.

And to be honest, there are probably other ones, I just cannot recall. Majority of them early on were definitely rectourethral fistulas, though.

Q. Besides the patent infringement

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case where you've issued an expert report, have you issued an expert report in any other case, setting aside the present case that we're here for today?

A. No. That's the only one.

Q. Was Coloplast the plaintiff or defendant in that patent infringement case?

A. I'm not that great on legal terms, but they were -- Coloplast was suing GMD for infringement so I assume that's plaintiff.

Q. Do you have transcripts of your deposition or trial testimony from the Coloplast case?

A. No, I do not. Those have all been returned to Coloplast. I have reviewed them but they all were returned to -- not Coloplast. The legal firm that was representing them.

Q. So you reviewed the deposition transcripts and trial transcripts in your Coloplast case?

A. Only the deposition, not the trial.

Q. Did you make any corrections to

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those deposition transcripts?

A. We had -- there were clarifications so -- an errata or whatever you call that form was filled out. I read over it. There were spelling errors, grammar errors, those types of things.

Q. Any substantive changes you recall?

A. According to me and according to what the lawyer told me --

Q. I don't want to know about the lawyer, just you, in your mind, as a surgeon.

A. There would be one where the -- the question came up and I misunderstood the question and then we corrected it in the form of the deposition. And so we went back, I went back, and made sure it was clear that this was a misunderstanding.

Q. Do you recall the question and your answer?

A. Yes, I do.

Q. What is it? Or strike that.

What was it?

A. And can I disclose that? I

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don't --

Q. It was in a deposition.

A. It was in a deposition.

Q. I don't see why not.

Was the deposition sealed?

MR. ANDERSON: Unless it's filed under seal. I don't know.

BY MR. SNELL:

Q. Well, you gave trial testimony.

A. Yeah.

Q. Did you give trial testimony and opinions that concerned this errata --

A. Yes.

Q. -- change or issue?

A. No, not the trial, that issue did not come up. The GMD did not challenge the change. I mean, I know what it is. I just want to make sure I can talk about it.

Q. Do you have any basis or reason to believe that the transcript was sealed?

A. No. But I'm not a lawyer so I --

MR. ANDERSON: Objection. He wouldn't know that.

THE WITNESS: Yeah. I don't know.

BY MR. SNELL:
Q. When you reviewed it, did you see any designation that the transcript was confidential?
A. Many of the documents -- many of the documents had "confidential" on it.
Again, I'm not trying to be difficult.
Q. That's okay.
A. I know exactly what it is and I could tell you. I don't --
MR. ANDERSON: If he feels like it's ground-breaking stuff, we'll figure it out after the deposition.
MR. SNELL: No. Don't worry about it.
THE WITNESS: Okay.
BY MR. SNELL:
Q. Have you ever issued any expert Affidavits?
A. I don't know what that is.
Q. It's a written document where, it can be like a report except you swear under penalty of perjury that things you wrote and said in the Affidavit are true and correct,

to the best of your knowledge and belief.
A. I don't recall ever doing that, no. I would think I would remember something like that but I don't recall that.
Q. Besides this matter, are there any cases in which you expect to testify in with regard to the use of transvaginal mesh?
A. No.
Q. How did you come to be retained in this litigation?
A. Mr. Anderson contacted me.
Q. When was that?
A. September of last year, 2011.
Q. Besides Mr. Anderson, can you tell me the names of any other attorneys you've spoken with on behalf of the plaintiffs?
A. Mr. Adam Slater, Mr. John Restaino. I mean, if you want to know everybody that I can think of, Mr. Tom Cartmell. And I don't recall. There may have been another one I don't recall. Those are the ones that I can think of.
Q. Now, you've obviously met Mr. Anderson and Mr. Restaino.

Have you met any of the other lawyers in person?
A. Yes, I've met them. I don't know their names. I mean, I've been sitting in here for a couple of days and they all come walking in and talk to me. I don't know who they are. I mean --
MR. ANDERSON: Including Bill.
THE WITNESS: So, again, I cannot state my list is complete.
BY MR. SNELL:
Q. What is your rate of compensation?
A. 700 an hour.
Q. And how many hours have you billed?
A. I have no idea. I don't keep track.
MR. SNELL: Mr. Anderson, do you have a list of the number of hours he's billed and paid?
MR. ANDERSON: Yeah. We submitted that back in October to Kelly Maha and Mary Ellen with our other notices of materials reviewed, hourly rate, number of

hours to date, total amount paid was all submitted on I believe October 21st.
MR. SNELL: Is there a chance we can get that on the break? I don't have that. I have the list of disclosures and I went through them and I saw --
MR. ANDERSON: Off the record.
(Discussion off the record.)
MR. SNELL: Back on.
BY MR. SNELL:
Q. Can you give me an estimate of the number of hours you've spent?
A. I can't give you an accurate estimate because this has been over roughly a year now and many months. There's no -- so I don't know.
Q. Has your rate of compensation always been $700 per hour for your work in this matter?
A. Yes.
Q. Do you have a separate compensation rate for testimony?
A. No.
Q. Do you have a separate compensation rate for if you present

testimony at trial?
A. No.
Q. Have you attended any meetings where other experts for the plaintiffs have been present?
A. Experts for the plaintiffs.
THE WITNESS: That's your side.
MR. ANDERSON: Yeah.
THE WITNESS: I pointed to Doctor -- Mr. Anderson.
To the best of my knowledge, no. But we attend -- there's an overlap of meetings, uro-gyne and female urology, that overlaps. I do not recall ever meeting them in person, no.
BY MR. SNELL:
Q. Have you ever attended any meetings focused on this litigation with other experts for the plaintiff?
A. No.
Q. Have you ever spoken with or communicated with in any manner any other expert for the plaintiff in this litigation?
A. Yeah. With Dr. Weber.
Q. When was that?

A. It was on a Saturday roughly -- I'd have to look at the calendar. I would be able to tell you exactly if I looked at the calendar. A week and a half or so ago, something like that.
Q. November 3rd sound right?
A. Again, I'd have to look at the calendar. I -- days are all a blur right now.
Q. Saturday before last.
A. Today -- it would have been the Saturday before that. That sounds about right. And she was involved in a conference call.
Q. Who all was on that conference call?
A. Just Mr. Slater, and then Dr. Weber showed up half hour into the conversation.
Q. What did you say to Dr. Weber?
A. It was a half-hour conversation. I mean, I said hello to start off with and then we talked from there.
Q. Tell me everything you recall discussing with Dr. Weber.

A. Okay. I asked her about the drive from Baltimore down. I wanted to know if there was traffic, which she said there was none. I complimented her on her manuscripts that she's written.
Mr. Slater talked a lot and wanted to know her opinion on interstitial cystitis, which she then deferred to me since in urology we tend to deal with that more.
I then discussed diagnostic criteria for interstitial cystitis. And we talked about dates of when she was going to give her deposition and then we talked about dates of when I was giving my deposition. And that's pretty much all I recall. That is all I recall.
Q. You mentioned a conversation about the drive from Baltimore down? Were you in Baltimore?
A. No. No. She -- from what I recall, Adam said she just drove down from Baltimore. Or up. Where is Baltimore? Baltimore is south.
Q. Baltimore is south.

MR. RESTAINO: South.
THE WITNESS: I thought she said she drove in from Baltimore.
MR. SNELL: Okay. Just the down threw me off, that's all.
THE WITNESS: Yeah. I'm an L.A. boy and Minnesota, so the East Coast states are too small. I don't know where they are.
BY MR. SNELL:
Q. Now, you complimented Dr. Weber on the manuscript she had written; is that correct?
A. Manuscripts.
Q. Scripts.
And what manuscripts were those?
A. I'd have to look at the -- the exact title of them. The -- there was the original one that she was involved with defining prolapses, and then the other one I believe the first author was, it was like Chmielewski, something like that. I'd -- again, I'd have to look at the -- I know the content of the paper but not the exact

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title.
Q. Well --
A. It was redefining prolapse.
Q. And how was the prolapse being redefined in the paper? Or strike that.
How was the prolapse redefined in the manuscript by Dr. Weber?
A. Well, I'd have to get out the paper and we'd have to go over it.
Q. Just your general recollection.
A. Well, again, that was a very large paper with a lot of details in it, but what they were doing -- and it's in my expert report in a great amount of detail so that would probably be the best way, to go to it. Because off the top of my head, I'm not going to do the paper justice.
Q. But you said you recall complimenting Dr. Weber on the manuscript that she was involved in where she and others redefined prolapse.
A. No. All I said was, is, I've read your papers and they've -- I've appreciated your work. Roughly, that's the statement I made. We did not go into detail

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as far as the paper itself, but that's what I was referring to.
Q. So you appreciated Dr. Weber's work in redefining prolapse.
A. I think it's a -- I did not state that. That was my underlying intent, though.
Q. And was the manuscript that you're referring to Chmielewski, C-H-M-I-E-L-E-W-S-K-I, Walters, Weber, et al., "Re-analysis of a Randomized Trial of Three Techniques of Anterior Colporrhaphy Using Clinically Relevant Definitions of Success," Journal of Obstetrics and Gynecology, 2011?
A. That is correct.
Q. Besides your expert reports in this case, have you done any other analyses on the use of transvaginal mesh?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Well, transvaginal mesh -- you mean -- analyses, what do you mean as far as -- I need clarification. Studies? Expert reports?

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What?
MR. SNELL: Fair question.
BY MR. SNELL:
Q. Have you done any other expert reports on transvaginal mesh besides the ones in this matter?
A. No. The only thing that would be close would be that patent infringement case. But, again, that was not dealing with meshes specifically.
Q. Have you done any meta-analyses involving the use of transvaginal mesh?
A. No.
Q. Have you done any randomized, controlled trials involving the use of transvaginal mesh?
A. No.
Q. Have you done any randomized, controlled trials involving the use of mesh --
A. No.
Q. -- in any application?
A. No.
Q. Have you done any meta-analyses involving the use of mesh to treat prolapse?

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A. No.
Q. Have you performed any analyses comparing the use of transvaginal mesh to other treatment, other surgical treatment options to treat prolapse?
A. Well, analyses is a very broad term; therefore, the answer would be yes.
Q. And can you tell me what analyses you have done?
A. That would be reviewing of manuscripts, formulating papers, offering public opinion. No, that's not the right phrase. Statements regarding meshes.
Q. Have you ever been involved in a clinical study that used transvaginal mesh to treat prolapse?
A. No.
Q. Have you ever been involved in a clinical study that used transvaginal mesh to treat stress urinary incontinence?
A. Depends what you're defining clinical trial as.
Q. How do you define a clinical trial?
A. Well, clinical trial is a

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nondescript or nonspecific term.
We are doing analyses and studies on management of mesh complications. And just to clarify your previous question, that would also include transvaginal POP meshes as well as urinary incontinence meshes. And that's dealing with the laser, dealing with the urologic complications and perforations. That is an ongoing process.
Q. Have you done any retrospective cohort studies involving the use of transvaginal mesh?
A. Well, if that involves anti-incontinence procedures, yes.
Q. And what study or studies were those?
A. Those would be presentations we've made over the years. I'd have to get my CV out and review those. But dealing with the efficacy -- the one specific I can remember is the suprapubic ARC or SPARC by EMS. That's the one I can recall.
I mean, we've done robotic sacrocolpopexy data, which is involving,

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obviously, abdominal mesh. I'd have to look at my CV to give you a complete list, though.
Q. Do you have your CV here today?
A. I do not have a copy, no.
Q. Have you been involved in any prospective studies involving the use of mesh?
A. No.
Q. Have you performed any randomized, controlled trials with the robotic sacrocolpopexy?
A. No.
Q. Have you done any prospective studies involving the robotic sacrocolpopexy?
A. Did you just ask that? I thought it was the same question.
Q. I'm sorry. If I did, I apologize. Let me back it up and just ask it again. It's a little different.
A. Okay.
Q. Have you performed any prospective studies involving robotic sacrocolpopexy?

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A. No.
Q. When was the last time you performed a robotic sacrocolpopexy? I mean you as the lead surgeon.
A. It would have been -- I'm just going to give you a guess. It was in the past month. That may or may not be completely accurate. It would have been roughly that time frame.
Q. So in the last month you believe you performed a robotic sacrocolpopexy?
A. Well, we're -- we're a team that performs it. So, yes, I am -- I am the lead surgeon, I am the primary surgeon, but there is a team. And it's roughly within the past month.
Q. And I assume you used synthetic mesh in that robotic sacrocolpopexy?
A. Correct.
Q. Was that a polypropylene mesh?
A. Correct.
Q. And the sacrocolpopexy was performed to treat prolapse?
A. Correct.
Q. Was it a case of recurrent

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prolapse?
A. I don't -- I don't recall the details on it.
Q. Do you remember which manufacturer's polypropylene mesh you used in this robotic sacrocolpopexy that you performed within the last month?
A. It was American Medical Systems, abbreviated AMS, the IntePro, E-N-T-E capital P-R-O.
Q. Are you specifically credentialled by the Mayo Clinic to use polypropylene mesh?
A. I'm not aware of there being a credentialling process for use of mesh. I am credentialled for all female urology and prolapse.
Q. So you can perform any procedure you see fit to treat prolapse at Mayo Clinic, under their credentialling guidelines.
A. Excluding uterine prolapse. I do not perform that.
Q. So am I correct that Mayo Clinic credentialled you to allow you to perform

prolapse surgeries that include the use of synthetic mesh?
A. No. They have credentialled me or they have approved my credentials for all prolapse repair, transvaginal or transabdominal, including robotic and laparoscopy, excluding uterine prolapse and hysterectomy.
Q. And did Mayo Clinic credential you to perform repairs for stress urinary incontinence?
A. Yes.
Q. Did Mayo Clinic specifically credential you for the use of synthetic mesh to treat stress urinary incontinence?
A. I don't recall --
MR. ANDERSON: Object. Objection.
Go ahead.
THE WITNESS: I don't recall the specifics of it other than they say I have to provide documentation that I know how to treat stress urinary incontinence. I do not recall specifically a mesh being involved in there.

BY MR. SNELL:
Q. Did you provide documentation that you know how to treat prolapse to the Mayo Clinic as part of your credentialling?
A. That would have been back in 2000. And, as I recall, we had to have a letter from my fellowship director documenting the number of cases, complexity of cases, variety of cases that I had done during fellowship to ensure that they had reached an acceptable number to show talent or competency, I suppose.
Q. When you performed this last robotic sacrocolpopexy case involving polypropylene synthetic mesh, did you select the specific mesh or do you just -- how do you requisition that mesh?
A. Early on, years ago, so it would have been seven, eight, nine years ago, when we were trying to determine this procedure and how we were going to perform it, I reviewed multiple different meshes.
Then it goes to an acquisition committee, so to speak, who then contacts the various different companies for

purchasing. And there were several that I was okay with, and then for financial reasons the IntePro was chosen. There's...
Q. And was Prolene mesh one of the meshes that you were okay with?
A. They were all Prolene meshes, polypropylene meshes.
MR. ANDERSON: You got that clarification? You said Prolene, he said polypropylene, so maybe we can do --
MR. SNELL: Yeah.
BY MR. SNELL:
Q. Did you evaluate Gynemesh® PS during this review of meshes?
A. To the best of my knowledge, no.
Q. Why not?
A. I wasn't familiar with the product.
Q. And this would have been approximately seven or eight years ago?
A. It would have been our first robot -- I'll back up.
I was originally trained to use Gore-Tex sacrocolpopexies during my fellowship. So when I returned on staff, I

continued to use Gore-Tex; however, I found problems with it of erosion, extrusion -- excuse me. Not erosion. Extrusion into the vagina. So it was roughly 2002, 2003 is when I made the changeover to polypropylene.
Q. Your original training where you used Gore-Tex, was that your fellowship?
A. Correct.
Q. And that was your fellowship at Baylor.
A. Baylor, correct. In Houston, Texas.
MR. SNELL: Why don't we take a little break.
(Recess, 11:03-11:18 a.m.)
BY MR. SNELL:
Q. We spoke a little earlier about the conference call you attended with Dr. Weber.
What did Dr. Weber say to you?
A. She didn't speak. I mean, she spoke to me but it was nothing of substance other than that she felt my knowledge of interstitial cystitis and practice was more involved than hers or just because of my

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practice, the variations between the two of us.

We talked about patients that I had seen, and she had mentioned, you know, as far as her seeing patients with pelvic pain, I believe.

Again, it was -- it was -- the majority of the time was actually me talking, not necessarily her.

Q. Have you been on any other phone calls with any of the plaintiffs' experts besides this one conference call?

A. No. Just Miss Weber or Dr. Weber.

Q. Have you had any other form of communication with any expert for the plaintiffs?

A. No. Communication, I mean, I've read depositions but no verbal or face-to-face communications with any plaintiff experts.

Q. Any E-mails or letters --

A. None.

Q. -- correspondence between you and any other plaintiffs' expert?

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A. None.

Q. And which depositions of the plaintiffs' experts have you read?

A. I'd have to look at the list. My supplemental list would be most thorough.

Klinge. I'm not pronouncing that correctly, but it's the one I can think of off the top of my head. But, again, I'd have to go look at it.

Q. Have you read Dr. Weber's deposition transcript?

A. Yes.

Q. When did you read Dr. Weber's deposition transcript?

A. It was a few days after or following the deposition.

Q. Besides Drs. Klinge and Weber, can you think of any other plaintiffs' expert deposition transcripts you've read?

A. I'd have to get my supplemental report out. If we have that, I can go through the list. Because it's a fairly long list. And I have a -- I have a copy of my --

MR. ANDERSON: No. Just --

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you've answered the question.

BY MR. SNELL:

Q. Do you have a copy handy?

A. Yes, I do.

MR. ANDERSON: You mean of the supplemental?

THE WITNESS: The supplemental.

MR. SNELL: Whichever the doctor wants to look at.

MR. ANDERSON: Oh, okay.

BY MR. SNELL:

Q. Just so the record is clear, you're looking at your supplemental expert report, which is dated what?

A. This is dated November 7th. It is the copy that has been signed by me. I don't have it signed.

THE WITNESS: You have -- do you have an official one?

MR. ANDERSON: Yeah.

That's the one I handed to you this morning, Burt.

THE WITNESS: The only one that is signed by me is the only one that is the correct -- this is it. So the one you just

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handed me is the official one or the correct one, let's say.

And so experts -- excuse me. Can you ask your question then again?

MR. SNELL: Sure.

Let's just make the record clear.

I'm going to mark Deposition Exhibit Number 2 the supplemental report that I handed you that you have signed, just so we're clear on the record.

(Exhibit Elliott-2 was marked for identification.)

BY MR. SNELL:

Q. Is that okay, Doctor?

A. Correct.

So the report I have, which is marked as Exhibit 2, is the only one that is that one that I have signed and --

MR. ANDERSON: That's -- just answer the question.

BY MR. SNELL:

Q. My question was, besides Drs. Weber and Klinge, what other deposition testimony have you reviewed of the

plaintiffs' experts?
A. That would be it.
Q. When did you review Dr. Klinge's deposition testimony?
A. Oh, I can't recall. After -- after it became available at some point in time, but I reviewed many in different days. I can't recall.
MR. SNELL: Off the record for a second.
(Discussion off the record.)
BY MR. SNELL:
Q. While we're talking about reports, let's just make sure I have a full list of all the reports you've authored in this case.
The first I have is your June 15th, 2012, general report in this matter; is that correct?
A. Correct. Yes.
Q. And on November 8th, 2012, it was served on defense counsel and it included annotations or citations; is that correct?
A. Correct.
Q. Are there any changes besides

adding in the annotations and citations to that June 15th, 2012, general report?
A. Absolutely none that I'm aware of.
Q. And in the June 15th, 2012, general report you did not issue any case-specific opinions with regard to Linda Gross; correct?
A. That is correct.
Q. And in your June 15th, 2012, general report you did not issue any case-specific opinions regarding Pamela Wicker; correct?
A. Correct.
MR. SNELL: For the record, the defense has filed a Motion to exclude the November 7th, 2012, report issued by Dr. Elliott.
BY MR. SNELL:
Q. And, Dr. Elliott, this November 7th, 2012, report which we marked as Elliott Exhibit Number 2, this is the first time you've issued opinions with regard to Linda Gross; correct?
A. Correct.

Q. This is the first time you've issued case-specific opinions with regard to Mrs. Wicker; correct?
A. Correct.
Q. Before issuing your June 15th, 2012, general report you did not look at any medical records for Mrs. Gross; correct?
A. To my knowledge, no.
Q. Am I correct?
A. To the best of my knowledge, no, I did not review any records of Miss Gross.
Q. And before issuing your June 15th, 2012, general report you did not issue -- sorry -- you did not review any medical records involving Pamela Wicker; correct?
A. To the best of my knowledge, you are correct, I did not review any.
Q. Prior to issuing your June 15th, 2012, general report you did not review any of the depositions in the Linda Gross case; correct?
A. Yeah. To the best of my knowledge, no, I did not review any.
Q. And prior to issuing your June 15th, 2012, general report you did not

review any depositions in the Pamela Wicker case; correct?
A. Correct.
Q. Prior to issuing your June 15th, 2012, general report you did not review any radiology on Linda Gross; correct?
A. Correct.
Q. Prior to issuing your June 15th, 2012, general report you did not review any urologic studies on Linda Gross; correct?
A. Correct.
Q. Prior to issuing your June 15th, 2012, general report you did not review any radiology on Pamela Wicker; correct?
A. Correct.
Q. Prior to issuing your June 15th, 2012, general report you did not review any urologic studies on Pamela Wicker; correct?
A. Correct.
Q. The third and last report that I have is dated November 14th, 2012, which is a letter by you addressed to Mr. Anderson stating, I have reviewed the following documents, which further support my opinions in this case as set forth in my original

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report.
A. May I see it?
Q. Sure.
MR. ANDERSON: For the record, I'll just stipulate that I sent that because I saw that we had inadvertently left two off, which is what the cover E-mail said when I sent it to you guys yesterday.
THE WITNESS: So your question -- I -- I'm sorry. What's your question?
BY MR. SNELL:
Q. Is this the third and last report or supplement that you have?
A. Yes.
Q. When you say, I have reviewed the following documents which further support my opinions in this case as set forth in my original report, when you say "original report," do you mean your June 15th, 2012, report?
A. Yes.
Q. I'm going to hand you what's been marked as Exhibit Number 1. It's your Notice of Deposition.
Have you ever seen that

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document before?
A. No, I have not.
Q. Can you turn towards the back, the appendix? It asks that you bring certain materials to the deposition.
A. What page are we on? Six?
Q. Let me get there and follow with you.
Let me take a look at it, Doctor.
A. (Witness complies.)
Q. Under all this paper, I seem to have lost mine.
So you're correct, Doctor, Page 6 through 9 asks that you bring certain materials to the deposition.
MR. ANDERSON: Well, just to clarify, I have to object, that it's sent to me, so it asks me to bring. And he's already said that he didn't see this.
MR. SNELL: Besides the reports and the compensation information, are there any other materials that are forthcoming in response to the Notice of Deposition?
MR. ANDERSON: No.

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MR. SNELL: And what's the basis for the non-production?
MR. ANDERSON: It's my understanding that everything that we are required to produce has been produced.
BY MR. SNELL:
Q. Doctor, I'd like to -- you can set that aside.
I'd like to talk to you about your background. You did your medical school at Loma Linda?
A. Correct.
Q. And you graduated in 1993?
A. Yes.
Q. And during your medical schooling did you do a rotation in obstetrics and gynecology?
A. Yes.
Q. In your medical school training at Loma Linda did you learn human anatomy?
A. Yes.
Q. In your medical school training did you learn the anatomy of the female pelvic floor?
A. In a superficial manner, yes.

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Q. Did you learn the location of the nerves in the pelvic floor in your medical school training?
A. In a very general way, yes.
Q. Did you learn the location of the blood vessels in the pelvic floor during your medical school training?
A. Again, in a very general way, yes.
Q. Were you taught about pelvic organ prolapse during your OB-GYN rotation during medical school?
A. I don't recall.
Q. What do you recall about the subjects you were taught on in your OB-GYN rotation during medical school?
A. That giving heroin to a mother that's giving birth is not a good thing. We saw that all the time at the county hospital. So if you want a stark memory, that's it.
The OB-GYN rotation, depending upon where you were, would also divide up with peds, so it was not a true specific. So we just followed the babies afterwards on

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heroin and things.
Then I did a GYN-ONC, which is a GYN cancer rotation, two weeks. And so that was dealing with ovarian, uterine, vaginal cancers.
Q. Did you see any surgeries -- strike that.
Did you see any gynecologic surgeries during your medical school?
A. Yes.
Q. Which were they?
A. Specifically limited to, again, GYN-ONC just because -- hysterectomies from malignancies, debulking procedures for malignancies just because that's the rotation I was assigned to. Others would have different experiences than I.
Q. Did you see any C-sections performed?
A. In the OB, but that was not GYN.
Q. Did you see episiotomies performed?
A. Yes.
Q. Did you see surgeries for stress urinary incontinence performed during

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medical school?
A. To the best of my knowledge, unfortunately, we're going back 20-some years now, I do not recall any anti-incontinence procedures in OB-GYN -- or it would be GYN, actually -- or urology.
Q. Did you see any prolapse surgical procedures during your medical school?
A. I don't recall any, no.
Q. You then did an internship in general surgery at Mayo in 1994?
A. '93 to '94, yeah. One year.
Q. How did you come to choose to do that general surgery internship?
A. I didn't have a choice. Every urology residency you have to do general surgery. You either do one or two years or some of them will do one and a half years. At Mayo it's one year. So, again, there was no choice in the matter.
Q. And what did that internship consist of? What types of surgeries did you see or were you involved in?
A. You do rotations varying between 6 to 12 weeks in vascular, colorectal,

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transplant, trauma, and there's something else. There was one more rotation in there. I can't recall. There's one more rotation. It was basically just covering the entire abdomen.
Q. And did you perform surgeries during your internship or were you just watching or helping out in some manner?
A. You're an assistant. You may perform -- put in some stitches, but you're not doing much.
Q. During your internship in general surgery did you see any hernia surgeries?
A. Yes.
Q. Did you help assist in any hernia --
A. Yes.
Q. -- hernia surgeries?
A. Excuse me. Yes.
Q. Did these hernia surgeries involve the use of mesh?
A. To the best of my recollection, no. And I think that's fairly accurate. It was an older general surgeon who did not believe in meshes, actually.

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Q. Did you see or were you involved in any hernia surgeries that involved mesh during your internship?
A. I don't recall any.
Q. Did you see or were you involved in any prolapse surgeries during that internship?
A. For pelvic organ prolapse?
Q. Yes.
A. No.
Q. You hesitated there for a second.
Was there some type of other prolapse procedure that you saw during your internship?
A. Well, there's, you know, mitral valve prolapse, diaphragmatic.
Prolapse is just a generic term, so I just wanted to make sure I was clear what you were talking about.
Q. That's fair. Thank you for clarifying that.
I'm not here talking about mitral valve prolapse or any other valve prolapse. When I say prolapse today and tomorrow, I just want you to assume that I'm

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talking about pelvic organ prolapse. Okay?
A. I'll still ask for clarification.
Q. That's fine. But --
A. Sure.
Q. -- I'm going to tell you I'm not getting into mitral valves.
Did you see any surgeries for urinary incontinence during your internship?
A. Male or female?
Q. Either.
A. Probably -- probably male, because you do actually do a six-week urology rotation. I can't recall exactly. The staff I worked with did deal with male incontinence.
Q. During your internship in general surgery were you trained on anatomy?
A. Yes.
Q. And you were trained on that anatomy as it has bearing upon performing surgical procedures in those areas?
A. Correct.
Q. During your internship were you trained on the location of nerves in the pelvic floor?

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A. Not that I recall, no.
Q. During your internship were you trained on the location of blood vessels in the pelvic floor?
A. Yes.
Q. During your internship were you trained on the location of ligaments and connective tissues within the pelvic floor?
A. Yes.
Q. For example, were you trained on the location of the sacrospinous ligament during your internship?
A. I can't state that specific ligament, but in colorectal surgery I was working in the same general region, and the aggressive surgeries with malignancies, those ligaments in that general region would have been exposed and shown.
Q. And that would include the --
A. Or --
Q. I'm sorry. I didn't mean to cut you off. Were you going to say something else?
A. I was. I forgot what I was going to say, though.

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Q. I apologize.
Would that have included the sacrospinous ligament?
A. Yes.
Q. Would that have included the arcus tendineus?
A. Most likely, not, because that would be more superficial. Colorectal surgeons would be working deeper in the pelvis.
Q. Would you have been trained on the location of the arcus tendineus during your medical school training, then?
A. It would have been shown and discussed in anatomy lab, cadaveric labs, and probably in the GYN-ONC rotation too.
Q. Would the location of the sacrospinous ligament also have been shown and discussed during the cadaver labs during your medical school training?
A. Yes.
Q. You then performed a residency in urologic surgery at Mayo from 1994 to 1999; correct?
A. Correct.

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Q. Is that a standard five-year program or did -- why did it take five years?
A. Well, the residency, urology residency, when I did it, was a total of six years, so from start to finish is six years.
Some programs will do one or two or one and a half years of general surgery. So it just happens to be at Mayo you do one year general surgery, five years of urology. So there would be some minor variation of it around the country.
Q. Okay.
A. But it's all six years. Now it's down to five years, actually.
Q. And during your urologic surgery residency did you see prolapse surgeries?
A. In urology? Yes.
Q. During your urologic surgical residency at Mayo from 1994 to 1999 did you also see urinary incontinence surgeries?
A. Yes.
Q. Now, during your urologic surgery residency, with regard to urinary incontinence procedures, how much assistance

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would you give during those surgeries?
A. That depends upon your level of training. At times, you will do minimal, at times, you'll do nearly the entire case. That depends upon your skill level and the surgeon you happen to be working with.
Q. For you --
A. That would depend, because I can't answer the question specifically. Because if I'm in the second year, I'm going to do a little bit; if I'm a chief, six years, I will do a lot or essentially the entire case with supervision, obviously.
Q. So as you got more and more experience, you were allowed to do more and more of the procedure.
A. As your experience and skill level advanced, you did more.
Q. Now, with prolapse surgeries during your residency does the same hold true, basically, that as your experience and skill level increase, you are able to perform more and more of the case?
A. Correct.
Q. What prolapse surgeries did you

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observe or participate in during your urologic surgery residency between 1994 and 1999?
A. Anterior colporrhaphy, posterior colporrhaphy, McCall's culdoplasty or Mayo culdoplasty. There's going to be subtle variations between those two. That should be it.
Q. So during your residency you didn't observe or perform any sacrospinous ligament fixations?
A. No.
Q. During your residency you didn't perform any sacrocolpopexies?
A. No.
Q. Do you know why you didn't perform any sacrocolpopexies at Mayo during your residency?
A. During my training, the female urology was somewhat in its infancy. The staff was not trained in that so did not do that, and they went to the GYN department to do those.
Q. During your residency did you have occasion to go to the GYN group and

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observe those surgeries for prolapse?
A. I don't recall ever doing that.
Q. During your residency what stress urinary incontinence procedures were you trained on?
A. Artificial urinary sphincter, Raz urethropexy, and autologous pubovaginal sling, cadaveric pubovaginal sling.
Q. During your residency can you estimate the number of colporrhaphies that you participated in?
A. Yeah. My female urology rotation was 1997 so I'll only give you a rough estimate. Maybe ten. And you asked, actually anterior?
Q. I just asked for either, for either anterior or posterior.
A. Oh. Combined, roughly ten anterior and ten posterior.
Q. How about the number of McCall's culdoplasty or Mayo culdoplasty, as you termed it?
A. It would be probably two or three.
Q. Was there a particular surgeon

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who trained you on the prolapse surgeries during your residency?
A. Dr. Lightner. Dr. Deborah Lightner.
Q. How do you spell her last name?
A. It's Lightner.
Q. Okay.
A. L-I-G-H-T-N-E-R.
Q. And then you went and did your fellowship at Baylor that we earlier discussed with regard to neurology, urodynamics and voiding dysfunction?
A. Correct.
Q. Why did you seek to do that fellowship?
A. That was -- I was asked to come back on staff, and so the chair and executive committee selected the program for me to go to which they would feel would give me the best education.
Q. Can you tell me what that course -- I'm sorry -- that fellowship course consisted of?
A. Uh-huh. It is voiding dysfunction, urinary incontinence with a

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Dr. Tim Boone, B-O-O-N-E, and where he managed the voiding dysfunction, incontinence and neuroanatomy. He was a neuro Ph.D., M.D. And then all the prolapses I did with the GYNs while he managed the incontinence. That's specifically why the program was chosen for me.

Q. And the prolapse surgeries you did during your fellowship were what?

A. Well, we -- we -- we did them all: Anterior/posterior colporrhaphies, the McCall's culdoplasty, sacrospinous fixation, abdominal sacrocolpopexy, perineorrhaphies, colpocleisis.

Q. Can you spell those last two for the court reporter?

A. Colpocleisis is a tough one. C-O-L-P-O-C-E-I-S. And that's not even going to be correct, actually.

MR. ANDERSON: C-L-E-I-S-I-S.

THE WITNESS: Do you know what? It's a tough one. There's E's and I's everyone. That's why we just say colpocleisis, say it fast and --

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MR. RESTAINO: And write it sloppily.

THE WITNESS: And write it sloppily, yeah.

It's a closure of the vagina, essentially.

BY MR. SNELL:

Q. And the perineo -- I missed it.

A. Oh, perineorrhaphy. I'd have to write that one out to be able to --

Q. Well, what did that consist of? You don't have to write it out.

A. That is a rebuilding of the peroneal body, usually which has been -- destroyed is a harsh term -- attenuated, thinned out due to multiple childbirths. So you rebuild it. It's right at the introitus of the vagina on the posterior aspect.

Q. And who was the surgeon who trained you on these prolapse surgeries?

A. Multiple surgeons because I worked with the GYN department at Baylor. I worked specifically with the chair, who I can't recall his name, and then another surgeon at Texas Woman's Hospital, again,

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who I cannot recall his name top of my head. Dr. Cone. Excuse me. I don't know his first name. Who he is the one who mainly taught me the sacrocolpopexy. But there were other surgeons in there.

Q. And during your fellowship training did you have training on the anatomy of the pelvic floor?

A. Yes.

Q. Was that in-depth training?

A. I would say very much so, yes.

Q. Did you have training on the nerves in the pelvic floor?

A. Yes.

Q. Did you have training on the blood vessels in the pelvic floor?

A. Yes.

Q. Did you have training on the ligaments and supporting structures in the pelvic floor?

A. Yes.

Q. How long was that fellowship?

A. 12 months.

Q. Did you also perform stress urinary incontinence surgeries?

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A. Yes.

Q. Which ones?

A. Autologous pubovaginal sling, cadaveric pubovaginal sling, artificial urinary sphincter.

Q. During your fellowship, when you were involved in the prolapse surgeries, were you the lead surgeon or were you, you know, second to one of the doctors which you identified?

A. The staff would be the lead surgeon technically, primarily surgeon; however, I would be the one doing the surgery with his or her assistance.

Q. Did you have patients fill out informed consents during your fellowship?

A. Yes.

Q. You agree that all surgeries have risks?

A. Yes.

Q. All pelvic organ prolapse surgeries have risks?

A. Yes.

Q. The risk with hysterectomies; correct?

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A. Yeah. I don't perform hysterectomies, but yes.
Q. You have been trained and you are aware as a medical physician that there are risks attendant to hysterectomy.
A. Yes.
Q. There's risks with episiotomies?
A. Yes.
Q. There's risks with Caesarean section surgery?
A. Yes.
Q. Is it correct that all prolapse surgeries have a risk of bleeding?
A. Yes.
Q. All prolapse surgeries have a risk of infection?
A. Yes.
Q. All prolapse surgeries have a risk to injury to other organs?
A. Yes.
Q. All prolapse surgeries have a risk to nerves?
A. Yes.
Q. All prolapse surgeries have a risk of pain; correct?

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A. Correct.
Q. All prolapse surgeries have a potential risk of dyspareunia; correct?
A. Yes.
Q. All prolapse surgeries have a potential risk of pelvic pain; correct?
A. Yes.
Q. What was the first mesh or graft material you ever used during your training?
A. The SPARC by AMS.
Q. And when was that?
A. Roughly 2002.
I'm going to have to actually after reading this go back and correct my answer because you said first mesh or graft material you ever used during your training. I understood the question as incontinence.
During my training, we used Gore-Tex on sacrocolpopexies. That's what I was originally trained with. So I misunderstood your question.
Q. That's okay.
The SPARC was for urinary incontinence; correct?
A. Correct.

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Q. First time you performed a sacrocolpopexy was during your fellowship at Baylor; correct?
A. Correct. Yes.
Q. And who trained you on performing the sacrocolpopexy with the Gore-Tex mesh?
A. Dr. Cone, C-O-N-E, at Texas Medical Center -- Texas Woman's Hospital.
Q. And the sacrocolpopexy that you -- strike that.
Did you perform a sacrocolpopexy with Gore-Tex mesh during your fellowship?
A. Yes.
Q. The sacrocolpopexy you performed with Gore-Tex mesh during your fellowship, was that to treat prolapse?
A. Correct.
Q. And you performed the sacrocolpopexy with Gore-Tex mesh to treat prolapse between 1999 and 2000; correct?
A. 1999 until roughly 2001, 2002. I don't remember when I made the switchover.
Q. I'm not going that far yet. And let me back up.

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The sacrocolpopexy procedures you performed with Gore-Tex mesh to treat prolapse during your fellowship was between 1999 and 2000; correct?
A. Correct. To June -- June 31st -- June 30th of 2000. That's when my fellowship ended.
Q. And when did it begin?
A. July 1st of '99.
Those are going to be rough dates but those are pretty accurate.
Q. Sound pretty exact to me.
A. You remember the year.
Q. Did you use any other mesh products besides the Gore-Tex mesh during your fellowship?
A. No. During the fellowship, the only mesh that I can recall using or synthetic agent was the Gore-Tex.
Q. And why did you use Gore-Tex mesh during the sacrocolpopexies performed during your fellowship to treat prolapse?
A. Because that's what the staff chose.
Q. In 1999 and 2000 during your

fellowship, when you performed sacrocolpopexies with Gore-Tex mesh, you were aware that there was a potential risk of mesh exposure; correct?
A. Yes.
Q. And you were aware during that same time period of your fellowship that mesh exposure with Gore-Tex mesh performed during sacrocolpopexy could lead to the need for re-operation.
A. Yes.
Q. And you are aware in 1999 and 2000 that any time you place a synthetic mesh, be it Gore-Tex or another mesh material, that there is a potential risk of mesh exposure; correct?
A. Yes, you're right.
Q. Do you guarantee success in the surgeries you perform with your patients?
A. No.
Q. Why is that?
A. Because I cannot guarantee success.
Q. Can any prolapse procedure be guaranteed to be performed 100 percent

successfully?
A. No.
Q. Have you ever guaranteed such performance?
A. As I said, no.
Q. Have you ever guaranteed patients that they will not have complications in association with a prolapse surgery?
A. No.
Q. Why is that?
A. Because you cannot guarantee it.
Q. And as a surgeon, you know that any time you perform a prolapse surgery, re-operation is a potential risk going into it; correct?
A. That is correct.
Q. And that can be a re-operation because of a failure of the prolapse surgery in performing its intended job to hold the prolapse; correct?
A. I -- I assume you're asking because of failure reoccurrence? Yes.
Q. And there can also be need for re-operation because a complication has occurred which necessitates further surgical

treatment; correct?
A. That is correct.
Q. And you learned that back during your internship in general surgery; correct?
MR. ANDERSON: Objection.
THE WITNESS: Well, no.
BY MR. SNELL:
Q. The surgeries will require --
A. Well, you --
Q. -- in some cases re-operation. That's my question.
A. Surgeries will require -- yes. I thought your original question was pertaining to prolapse, and I didn't learn that during my internship year. But all surgeries have the inherent risk of re-operation or complications.
Q. Now, during your fellowship, when you performed the sacrocolpopexy with the Gore-Tex mesh, you knew that mesh contraction was a potential risk; correct?
A. I would say actually I did not know that.
Q. When did you first become aware that mesh contraction could potentially

occur with the placement of a mesh?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Probably beginning in 2004, 2005.
BY MR. SNELL:
Q. So before 2004, you had not read any medical literature that talked about the potential risk of mesh contraction?
A. That is correct.
Q. How did you become aware of the potential risk of mesh contraction in 2004 or 2005?
A. Through some of the studies that I'd performed along with residents on the animal lab -- I'm sorry. Animal model.
Q. What type of mesh did you use there?
A. It was a polypropylene mesh.
Q. And was there mesh contraction with the polypropylene mesh that you studied in 2004 to 2005?
A. We saw increased fibrosis. We did not call it contraction because we didn't understand it at that point in time.

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Looking back at it, we realized there was contraction, but we called it fibrosis in our manuscripts.
Q. So when you did these studies -- what animal model was this?
A. Rabbit.
Q. Rabbit?
When you did these animal studies in the rabbit model back in 2004 or 2005, you saw fibrosis with the polypropylene mesh?
A. Correct.
Q. And in these rabbit studies in 2004 or 2005 that involved polypropylene mesh you didn't call what you saw mesh contraction; correct?
A. Correct.
Q. As you sit here today as an expert for the plaintiffs, it's your testimony that now you believe what you saw back then was mesh contraction?
A. Correct.
Q. Did you ever do any publications on these rabbit studies?
A. Yes. Two.

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Q. Did you ever write -- what journal were they published in?
A. I'd have to look. General -- I would suspect General Urology and Urology. It's in my CV.
Q. Did you ever issue a letter to the editor or an errata to your studies up to today, as we sit here today, to say what we previously described as fibrosis I now believe to be mesh contraction?
A. No.
Q. Why not?
A. Others have done it for me.
Q. Who has done it for you with regard to those two articles?
A. Dr. Chris Winters, president of the SUFU, Society of Urodynamics and Female Urology, goes around the nation speaking about, quoting that paper as one of the earliest manuscripts talking about fibrosis and contraction.
Q. He talks about it with regard to fibrosis and contraction?
A. Uh-huh. Uh-huh. Yes.
MR. ANDERSON: Is that yes?

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THE WITNESS: Yes. Yes. Correct.
BY MR. SNELL:
Q. What's his name?
A. Dr. Christian Winters, the president of the Society of Urodynamics and Female Urology.
Then there's Dr. Gregory Bales at the University of Chicago, who I've heard lectures quoting that paper. Those are the two I can think of off the top of my head.
Q. When did you first perform a hernia surgery involving mesh, if ever?
A. I never have.
Q. Never have?
In 2001 did you continue to use the Gore-Tex mesh with sacrocolpopexy?
A. Yes. I don't remember when I changed over to using polypropylene. It would have been, as I mentioned earlier, 2002, 2003. So, again, I don't recall exactly when.
Q. When you used the Gore-Tex mesh for sacrocolpopexy to treat prolapse between 1999 and 2001 -- strike that.

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When was Gore-Tex mesh FDA-cleared for the treatment of pelvic organ prolapse?
A. I have no idea.
Q. When you performed the sacrocolpopexies with Gore-Tex mesh to treat prolapse in 1999 to 2001, had it been FDA-cleared for the treatment of prolapse?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I have no idea. I would have trusted the company that it had been.
BY MR. SNELL:
Q. Well, you know Gynemesh® PS was the first mesh that was FDA-cleared for the treatment of prolapse; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I didn't know that.
BY MR. SNELL:
Q. You didn't know that?
A. That's what I said.
Q. You didn't know that in 2002

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Gynemesh® PS was the first mesh cleared by the FDA for the treatment of prolapse?
A. I've already answered that question.
Q. I'm asking a specific date now to see if this refreshes your recollection.
A. It does not, no.
Q. Would you agree that pelvic organ prolapse can be burdensome to many women?
A. Absolutely.
Q. Would you agree that it can affect their quality of life?
A. Absolutely.
Q. Women with prolapse can report feelings of heaviness or pressure?
A. Correct.
Q. They can report the feeling of a bulge or see an actual protrusion from their vagina; correct?
A. Correct.
Q. And this can be distressing to many women; correct?
A. Absolutely.
Q. Patients with prolapse can have interference with their sexual activity from

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the prolapse; correct?
A. Yes.
Q. And women with prolapse can have dyspareunia at baseline with that -- associated with that prolapse; correct?
A. Yes.
Q. And some women are actually not sexually active because of the effect their prolapse has upon them; correct?
A. Yes.
Q. And that can be because of the physical effects of the prolapse; correct?
A. As one of the factors, yes.
Q. But also the way the woman feels about herself because of the prolapse; correct?
A. Absolutely.
Q. And you know that because of your training; right?
A. Experience.
Q. You know that because of your experience?
A. Yes.
Q. But also your training; correct?
A. They're one and the same.

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Q. Patients with prolapse can have pain in their pelvic floor from changes to their pelvic floor musculature; correct?
A. Pain is highly unlikely to be associated with pelvic organ prolapse, and in the exception, there can be pain. That is rare.
Q. Some patients with prolapse are not sexually active because of factors associated with their partner; correct?
A. There are a lot of variables in that one.
Some patients with prolapse are not sexually active because of factors associated with their partner. Are we talking male or female? I mean, I guess I'm not following your question. I need that one rephrased.
Q. Well, let's back up, then.
Some patients with prolapse are not sexually active because of their prolapse; correct?
A. Yes. Correct.
Q. And some patients who are not sexually active who have prolapse may not --

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may be not sexually active because of partner factors as opposed to the factor specific to the prolapse; correct?
A. Okay. Thank you. I understand the question now.
Yes, you are correct.
Q. Treatment options for prolapse involve conservative and surgical measures; correct?
A. Yes.
Q. They involve the use of what's called a pessary; correct?
A. Yes, that is one option.
Q. Do you believe that option is appropriate in all patients?
A. No.
Q. And in the majority of cases treated conservatively -- strike that.
In the majority of prolapse cases treated conservatively, the condition does not get better; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Answering your question specifically, no. Pelvic organ

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prolapse tends not to improve. It does not necessarily worsen, however.
BY MR. SNELL:
Q. Some women do not want to use a pessary; correct?
A. Absolutely.
Q. And women who have pessaries need to be seen by their physician periodically to check on the pessary; correct?
A. Correct.
Q. And how often do you see your patients who use pessaries --
A. I don't see them --
Q. -- for the maintenance of them?
A. I don't see them -- I don't implant or deal with pessaries.
Q. Okay.
A. I refer them to our urogynecology colleagues.
Q. And you know some women are given pessaries as an option and they just refuse to use a pessary; correct?
A. You're correct.
Q. There can be vaginal discharge with pessaries?

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A. Yes.
Q. There can be vaginal odor associated with the use of pessaries?
A. Yes.
Q. There can be ulceration associated with the use of a pessary?
A. Yes.
Q. There can be bleeding associated with the use of a pessary?
A. Yes.
Q. There can be tissue erosion associated with the use of a pessary; correct?
A. Yes.
Q. And these are all potential complications from a pessary that you've known about since the time of your training?
A. Yes.
Q. And these symptoms may lead a woman to discontinue the use of a pessary; correct?
A. Yes.
Q. Do pessaries need to be removed and cleaned on a regular basis?
A. Yes.

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Q. The Gore-Tex mesh you used between 1999 and 2001, who was the manufacturer of that?
A. Gore-Tex.
Q. And what was the porosity of that Gore-Tex mesh that you used between 1999 and 2001?
A. I don't know.
Q. What was the flexural rigidity of that Gore-Tex mesh you used between 1999 and 2001?
A. I don't --
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I don't know.
BY MR. SNELL:
Q. What was the burst strength of that Gore-Tex mesh you used between 1999 and 2001?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I don't know.
BY MR. SNELL:
Q. What was the rate of the mesh exposure you saw with the Gore-Tex mesh

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between 1999 and 2001?
A. I don't recall.
MR. ANDERSON: We've been going about an hour and 20 and I think lunch will be here any minute, so I'm not telling you to stop now, I'm just suggesting that whenever you get to a good break, I think it's probably a good time to break. But continue, please.
BY MR. SNELL:
Q. During your fellowship you performed sacrospinous ligament fixation surgeries to treat prolapse; correct?
A. I assisted on those cases, yes.
Q. And you are aware that any time one is targeting the sacrospinous ligament, there is a potential risk to the pudendal nerves; correct?
A. Yes.
Q. And you knew this back in 1999 to 2000; correct?
A. Yes.
Q. And you know there's also a potential risk to the blood vessels that course in and around the pudendal nerves;

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correct?
A. Yes.
Q. And you knew this back in 1999 and 2000; right?
A. Yes.
Q. And when you were trained on targeting the sacrospinous ligament -- strike that.
When you were trained on targeting the sacrospinous ligament during the fixation surgery you were assisting in in 1999 and 2000, you were trained to target the sacrospinous ligament two finger breadths medial to the ischial spine; correct?
A. Actually, I don't recall because I never did pass the needle. The staff didn't feel it was safe for training on it, we only did a few, and so I never did it.
Q. No one ever said this is how far you should go medial to the ischial spine when placing a suture in the sacrospinous ligament fixation?
A. I'm sure they had mentioned it. I don't recall it.

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Q. Is there a particular textbook or surgical textbook that you received during your fellowship that you used?
A. I don't recall ever receiving one, no. I mean, I may have. I don't recall it.
Q. Did you recall looking at surgical textbooks during your fellowship to aid or assist you in performing prolapse surgeries?
A. Say no for prolapse surgeries.
Q. Were there general urologic or gynecologic surgical textbooks you used during your fellowship?
A. Yeah. Raz's I would suspect would be -- Raz's Transvaginal Surgery text.
Q. Back in 1999 and 2000, when you did your fellowship, when you performed the sacrocolpopexy, these were open abdominal sacrocolpopexies, I take it?
A. Correct.
Q. During your fellowship you were not trained on laparoscopic sacrocolpopexy; correct?
A. Correct.

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Q. During your fellowship you learned that there was a risk of bowel adhesion with sacrocolpopexy; correct?
A. Bowel adhesion to what?
Q. Or injuries to the bowels.
A. It is a theoretical risk, yes.
Q. What's an ileus?
A. Intestines that don't move, they're slowed.
Q. And did you learn during your fellowship that ileus is a potential risk with sacrocolpopexy?
A. No.
Q. When did you learn about that risk?
A. I already knew that coming into fellowship.
Q. Where did you learn about the risk of ileus with sacrocolpopexy?
A. Well, no. In general surgery you know with any abdominal procedure, regardless of what procedure it is, there will be an ileus.
Q. You did colporrhaphies during your residency and fellowship; right?

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A. Yes.
Q. And during your residency and fellowship you were aware that there was a potential risk of dyspareunia with colporrhaphies; correct?
A. Yes.
Q. And during your fellowship you were also aware that there was a risk of dyspareunia with other prolapse surgeries; correct?
A. Yes.
Q. Have you ever performed a sacrospinous ligament fixation --
A. I --
Q. -- with you as the principal surgeon?
A. As me as the primary surgeon, no, I have not.
Q. Have you ever performed a Prolift® surgery?
A. No.
Q. Have you ever performed a Prosima® surgery?
A. No.
Q. Have you ever performed surgery

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with Prolift+M®?
A. No.
Q. Did you ever undergo any of the Prolift® training?
A. No.
Q. I would assume you never underwent Prosima® training either.
A. Correct. I have not.
Q. Why did you switch from Gore-Tex mesh to polypropylene mesh?
A. Because I --
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: I was having too many problems with the Gore-Tex, specifically erosion. Extrusion. Excuse me. Vaginal extrusion.
BY MR. SNELL:
Q. And with the Gore-Tex mesh you were having that mesh extrude into the vagina?
A. Correct.
Q. And this was a potential complication that you were aware of during

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your fellowship; correct?
A. Yes.
Q. And when -- was this in 2002 or 2003, approximately, when you switched over to polypropylene mesh?
A. In that time frame. In the time frame from 2001 to 2003, it was in there somewhere.
Q. So sometime around 2001 to 2003 you began using polypropylene mesh in your sacrocolpopexies instead of Gore-Tex mesh?
A. That is correct.
Q. After 2003 what other meshes have you used during your sacrocolpopexies?
A. It's only been the polypropylene.
Q. How many sacrocolpopexies have you done since 2003?
A. Roughly 150.
Q. And those are sacrocolpopexies in which you were the lead surgeon?
A. Yes.
Q. Besides the AMS IntePro --
A. IntePro, yeah.
Q. -- that you earlier identified as the polypropylene mesh that you used for

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your sacrocolpopexies, can you tell me the other types of polypropylene meshes you've used for sacrocolpopexy?
A. In 2002, 2003, whenever I made the switchover, I -- as the best I can recall, we used an AMS product, American Medical Systems, and then when IntePro came out, started using IntePro. And I don't recall when that was because it was a minor variation between the product. And so I've only used, to the best of my knowledge, only used that product.
Q. In the time period of 2003 to -- strike that.
In the time period of 2002 to 2009 did Mayo have other manufacturers' polypropylene mesh that you could choose or did they only have AMS products, for whatever reason?
A. No. We could choose. We chose the product that we felt was the best and then it went to a selection committee, which then looked at the pricing. And if there were another variant that was the same price or less that we agreed with, we could go

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with that. But it wasn't like I was forced to use that product. I chose to use it.
Q. And the AMS, was it a particular AMS polypropylene mesh that you chose in 2002 that's different from the IntePro?
A. They --
Q. I'm not following it.
A. No. I understand. Because they had a product that was used for sacrocolpopexy, I don't recall the name of it, and --
Q. Can I stop you right there?
Before you came back from your fellowship, did they already have a mesh for sacrocolpopexies at Mayo?
A. No.
Q. Okay.
A. Well, I don't recall. Nobody that I know used it. The GYN department may have.
Q. Okay.
A. But not -- not anybody in my department.
Q. Okay.
A. So then AMS had a certain

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product, I don't recall the name. It was polypropylene. I used it. And then they came out with this IntePro, which is just a mild variation. I think they sutured the mesh together a little differently. And I used that. It was a very subtle difference.
Q. Was this a mesh that you cut to shape?
A. It was already Y-shaped. Actually, it's called IntePro Y-shaped mesh, as I recall. I haven't looked at the box in a long time. And it was Y-shaped. You trimmed the limbs to fit to the patient.
Q. The first polypropylene mesh you used for sacrocolpopexies, was that already Y-shaped or did you have to cut it into that configuration?
A. It was Y shapes. So by Y I mean there's a long strip and another strip comes off like this, so it's a Y like this, it's not a Y like this (indicating). Do you understand what I'm saying? As far as -- like a quarterback, you know.
Q. Right.
A. In the center.

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And that Y is then the -- the anterior limb is then sewn to this, the longer strip. So the only trimming that takes place is trimming the anterior and posterior arms for the length of the vagina and then trimming the sacrum part.
Q. What's the pore size on the AMS IntePro?
A. I don't know.
Q. What's the pore size on the initial polypropylene mesh you began using from AMS?
A. I don't know.
MR. ANDERSON: Lunch is here whenever you're ready there.
MR. SNELL: All right. This is good.
MR. ANDERSON: All right.
(Luncheon recess, 12:36-1:40 p.m.)
AFTERNOON SESSION
BY MR. SNELL:
Q. Dr. Elliott, you earlier testified that you were trained on the sacrospinous ligament fixation during your

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fellowship; correct?
MR. RESTAINO: Object.
THE WITNESS: I was shown the procedure. I was shown the procedure. I think it would be an exaggeration to say I was trained in it. Yeah, I was shown two times, two or three times.
BY MR. SNELL:
Q. During your fellowship you were shown the sacrospinous ligament fixation surgery; correct?
A. Yes.
Q. And you were aware from all the training that you had received up to date that the sacrospinous ligament fixation surgery to treat prolapse had been performed for decades by surgeons in the United States prior to the time of your fellowship; right?
A. Yeah. I don't know when the procedure was introduced. I knew it was a long-standing procedure. So I can't say decades or not. It was a preexisting surgery.
Q. Does it refresh your recollection if I say that Richter introduced the

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sacrospinous ligament fixation surgery decades before your fellowship? Is that --
A. No, it doesn't refresh my memory.
Q. -- consistent or inconsistent with your memory?
A. I just know it's been around a long time. I don't know who invented it.
Q. We can agree that the sacrospinous ligament fixation surgery has been around a long time; correct?
A. Yes. Yes. Correct.
Q. And there's a potential risk of urinary dysfunction with the sacrospinous ligament fixation surgery; correct?
A. Yes.
Q. And there is a risk of urinary dysfunction with other prolapse surgeries; correct?
A. Well, I mean, other, I mean, that's -- that's broad.
Q. It's meant to be broad.
A. Well, then make it specific.
Q. You can answer specific if you'd like. I just would like to know whether you would agree that urinary dysfunction is a

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potential complication with prolapse surgeries other than the sacrospinous ligament fixation; correct?
A. That is correct.
Q. Were you ever trained on the transvaginal placement of mesh to treat pelvic organ prolapse?
A. Transvaginal, no, I was not.
Q. And during your time at the Mayo Clinic were you ever trained on the transvaginal placement of mesh for prolapse?
A. No. No one at the Mayo Clinic uses mesh for prolapse, for transvaginal pelvic organ prolapse.
Q. I'm not talking about currently. I mean 2002 to let's say 2010.
A. Well, I thought I answered the question. No, I was not trained. No one at the Mayo Clinic uses transvaginal pelvic organ prolapse mesh.
Q. Ever, to your knowledge?
A. To my knowledge, ever. Yeah.
Q. You have been trained on the transvaginal placement of mesh to treat stress urinary incontinence; correct?

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A. Yes.
Q. And surgeons at the Mayo Clinic used transvaginal mesh to treat stress urinary incontinence; correct?
A. I was the first one. Yes.
Q. In fact, the majority of surgeons at the Mayo Clinic use transvaginal mesh to treat stress urinary incontinence; correct?
A. They --
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: They all do.
BY MR. SNELL:
Q. And at the Mayo Clinic the most common procedure done with transvaginal mesh placement to treat stress urinary incontinence is via the transobturator route; correct?
A. I can only speak to my practice because I don't know the other practices, the breakdown, but in my practice that is a correct statement.
Q. And you have described the transvaginal use of mesh via the transobturator route to treat stress urinary

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incontinence as a minimally invasive procedure, haven't you?
A. Have I -- have I used those words?
Q. Yes.
A. I -- I may have. I don't recall an incidence, but I would not deny it or say I haven't done it. I'd have to look at the reference.
Q. Well, you would agree that the use of transvaginal mesh to treat stress urinary incontinence via the transobturator route is a minimally invasive procedure; correct?
A. Has to be what you're comparing it to. If you're comparing it to the traditional autologous sling, by all means. If you're comparing it to DEFLUX injection for stress urinary incontinence, then it is much more invasive. So "minimally invasive" is a relative term. There is not a definition of that.
Q. And who trained you on the transobturator placement of slings to treat stress urinary incontinence?

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A. Well, I was familiar with the other approaches already, the much more invasive autologous, so the -- specifically the transobturator, that would have been in 2002, 2003. I took several courses with Carl Klutke, who was at St. Louis, Rodney Appell, who's passed away, used to be at Baylor, and there was somebody else that I learned with -- oh, and actually George Webster, there was a female urology course at some point in time that I took, talking with them, their feelings about it and the technique, and then watching surgical videos too.
Q. Where were those surgical videos from?
A. They were provided by Coloplast. Actually, at the time they were provided by Mentor Corporation.
Q. And you used polypropylene mesh during your stress urinary incontinence surgeries performed via the transobturator approach; correct?
A. Yeah, that's what I use now. Yes.

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Q. The traditional pubovaginal slings, that would include the autologous slings that you referenced a few minutes ago; correct?
A. Correct.
Q. And you would agree that compared to these autologous slings, the transobturator placement of polypropylene mesh to treat stress urinary incontinence is less invasive; correct?
A. I would agree. Comparing it as you -- just so we're clear, comparing it next to autologous slings, yes, it would be less invasive.
Q. Autologous slings to treat stress urinary incontinence are more invasive than the transobturator slings; correct?
A. Yes.
Q. And you have said that the traditional pubovaginal slings are rarely done nowadays because of the minimally invasive outpatient approaches with the transobturator approach.
A. Correct.
Q. The traditional pubovaginal

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slings include cadaveric slings; correct?
A. Uh-huh. Yes.
Q. As well as autologous, as you earlier testified; correct?
A. Yes.
Q. The autologous is the patient's own tissue; correct?
A. Yes.
Q. And that tissue has to be harvested from the patient; correct?
A. Yes.
Q. The harvesting of tissue from a patient for any type of sling material increases morbidity; correct?
A. Yes.
Q. And, in fact, for the sacrocolpopexy, surgeons sometimes use rectus fascia harvested and then that will be used to attach the vagina to the sacrum; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I'm not familiar with anybody doing that anymore because there have been studies by Brubaker, et al.,

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and others showing that autologous fascia does not work well for it, and that's why the transition over to synthetics. Some individuals may be doing it but there are some very good data against it.
BY MR. SNELL:
Q. There are very good data against the use of pubovaginal -- strike that.
There are good data against the use of autologous tissues for the treatment of prolapse via sacrocolpopexy; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I agree with that, yes.
BY MR. SNELL:
Q. But I am correct that at some point in time in the surgical history of treating prolapse surgeons did attempt to use autologous tissues in connection with their sacrocolpopexy procedures; correct?
A. That is correct.
Q. And ultimately, the data showed that that autologous tissue use in the sacrocolpopexy was not a feasible option

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long term; correct?
A. No. It's a feasible option long term.
Q. I'm sorry?
A. It's a feasible option long term.
Q. Well, what's the data you referred to by Brubaker, et al.?
A. That the failure rate was high.
Brubaker might have been the lead author. I can't say it was actually her. Et al. implies she's the lead author. I don't believe she's the lead author. She's probably the senior author. Just in case you want to find that article.
Q. Linda Brubaker's article?
A. Correct. Yes.
Q. What year? 2000?
A. Around that time period, yeah.
Q. I know which one you're talking about.
The autologous tissue can be digested by the body; correct?
A. That -- yeah, that is a theory of what happens to it. Yes.
Q. How was it that you came to use

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the Mentor sling for stress urinary incontinence? And what I'm talking about is specifically that sling as opposed to some other manufacturer of sling.

A. That was the transobturator sling specifically. Because I was already using the suprapubic, the SPARC, by AMS. Okay?

So in 2002, 2003 the transobturator was introduced to the United States. It had been in Europe prior to that time. So I was aware of it. Mentor Corporation, as I -- I believe was the first one to be able to offer it in the United States. At least I was -- I was contacted. So they came to me saying, hey, we have our transobturator sling here. It was the OB Tape.

Q. And for how long did you use the OB Tape?

A. 100 cases.

Q. What years?

A. Oh, I don't know. 2000 -- actually, I -- I just don't know. It was when it was introduced, 2003, 2004, '5, something like that.

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Q. So --

A. In that time frame.

Q. Until when?

A. Well, when I got the 100 cases. I do about roughly 80 to 150 cases a year. There's wide variation in my practice. And so however long it took me to do 100 cases.

Q. And after using the OB Tape did you switch to a different type of polypropylene mesh to treat stress urinary incontinence?

A. Yes. We went to -- well, no. I continued using the SPARC and then -- but that's suprapubic. And so then transobturator, then I started using the Monarc by AMS.

Q. So TVT-O was OB Tape, then --

A. Well, TVT-O was a product. I don't use TVT-O.

Q. The transobturator polypropylene meshes you've used have been OB Tape and then --

A. Monarc.

Q. -- Monarc.

A. Yeah. M-O-N-A-R-C.

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Q. And the suprapubic sling that you used was SPARC.

A. SPARC. And it stands for suprapubic ARC. And that's by AMS.

Q. Have you used any other type of -- is that also called the retropubic approach by some?

A. Retropubic, suprapubic. It gets -- it gets very confusing. Technically speaking, the TVT® type product would be retropubic. You go from bottom up. I've used because I felt it was in my hands easier to use, go top down, which is technically suprapubic. So it's confusing.

Q. Ultimately, urethral support is provided by a U-shaped polypropylene mesh sling with the suprapubic or the retropubic approach; correct?

A. You're absolutely right.

Q. And forgive me. When did you begin using the SPARC?

A. 2001, roughly.

Q. Now, you earlier testified that I believe you were the first surgeon at the Mayo Clinic who used the transobturator

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approach with the polypropylene sling. Is that correct or am I misstating?

A. To be correct, no question, I was the first to use suprapubic --

Q. Okay.

A. -- and transobturator, and I most likely was the first in the state of Minnesota to do both also. That I can't prove. That's what I've been told. It's one of those things.

Q. Okay.

MR. ANDERSON: Off the record.

(Discussion off the record.)

BY MR. SNELL:

Q. For the SPARC polypropylene mesh slings you began using in 2001, what was the pore size for that mesh?

A. I don't know the pore size, no.

Q. Do you know what the density in grams per squared is for that mesh is?

A. Density in --

MR. ANDERSON: Grams per meter.

MR. SNELL: In grams per meter squared.

THE WITNESS: No, I do not know

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that.
BY MR. SNELL:
Q. Do you know the thickness in millimeters of that mesh?
A. No.
Q. Do you know the flexural rigidity of that mesh?
A. Flex?
MR. ANDERSON: Objection.
BY MR. SNELL:
Q. Flexural rigidity.
A. Flexural rigidity? Do you have a math equation for that one? Maybe I'll figure it out. Flexural rigidity, because that's a math -- we can figure that on a math equation.
Q. As you sit here, do you know it?
A. No. That's why I was asking. So the answer then would be no.
Q. For the OB Tape mesh that you used beginning around 2002, do you know what the pore size was for that?
A. That is a very interesting question because with OB Tape -- I am not a materials expert so I have to be very clear

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on that. You look at OB Tape, hold it up to the light, there are essentially no pores in it. It's a thick band. Looks like a piece of ribbon, almost. So I can't answer your question; however, I can theorize it's tiny and -- go ahead.
Q. I didn't mean to interrupt you. Go ahead.
A. No. No.
Q. I thought you were done. I apologize.
A. I'm sorry.
Q. Do you know the density of the OB Tape mesh?
A. No, I do not.
Q. Well, what about the thickness of it; do you know that, by chance?
A. No, I do not.
Q. The mesh used in the Monarc transobturator, that's a polypropylene mesh; correct?
A. It's the same mesh as SPARC.
Q. So the same answers would hold true, then. You don't know what the pore size is of that mesh.

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A. Correct.
Q. Or the density or thickness; correct?
A. Correct.
Q. When was the last time you used polypropylene mesh to treat stress urinary incontinence?
A. Last week.
Q. You earlier testified that you switched from using Gore-Tex mesh to polypropylene mesh.
Why did you make that switch --
A. Because --
Q. -- specific to polypropylene?
A. Why did I switch to polypropylene?
Q. Yes.
A. Because that was the product that the AMS company came to me with.
Q. So you didn't do any individual scientific analysis of materials that were available --
A. I --
Q. -- at the time?
A. Sorry. No. I reviewed their --

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their product brochures, reviewed lectures provided to me by outside -- their clinicians, but no independent research, no.
Q. Have you ever used Vipro to treat pelvic organ prolapse?
A. Vipro. I'm not -- no.
Q. Do you know what Vipro is?
A. I believe it's a Vicryl-related absorbable type of mesh.
Q. Since you've been at Mayo Clinic, is it correct that the only meshes you have used since switching from Gore-Tex are polypropylene-based meshes for the treatment of prolapse?
A. I don't know what OB Tape was made of so --
Q. I thought -- I thought OB Tape was urinary incontinence.
A. It is. Did you say meshes?
MR. ANDERSON: He said --
MR. SNELL: Here. Let me give it.
BY MR. SNELL:
Q. Since you've been at Mayo Clinic, is it correct that the only meshes you have

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used since switching from Gore-Tex are polypropylene-based meshes -- I see where you're going. Okay. I should have put that in the beginning.

For the treatment of prolapse --

A. Okay. Yeah.

Q. -- since switching from Gore-Tex mesh, are the only meshes that you have been using the polypropylene-based meshes?

A. Yes.

Q. Besides harvesting flesh from the rectus fascia, surgeons also harvested flesh from patients, from their fasciae latae, to have an autologous band of tissue; correct?

A. Yes.

Q. When is the last time you did that to a patient?

A. Never.

Q. Why not?

A. Seemed very morbid to me.

Q. What they do is they create an incision for the fasciae latae --

A. No. I know how to do the procedure. That's not the -- my answer was

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not I don't understand it. I understand it. I said it's morbid.

Q. And it's morbid because they create an incision, they tunnel under the skin, use something like a Lausanne stripper to strip out the flesh to be used as an autologous sling; correct?

A. Yes.

Q. And, in your mind, that's a very morbid procedure; correct?

A. Yeah. Yes. Correct.

Q. And that's why you don't do autologous sling placements; correct?

A. I still will do autologous slings. They're rare. There's unique circumstances I will do it. I will not harvest from the fasciae latae, though.

Q. You will use cadaveric?

A. No. Autologous is autologous. Cadaveric is cadaveric.

Q. I'm sorry. Where would you harvest from?

A. The rectus.

Q. Rectus fascia?

A. Correct.

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Q. And even when you harvest from the rectus fascia, you tell patients that there can be additional complications or morbidity from that harvesting alone and apart from the procedure in which you're going to use that tissue; right?

A. Correct.

Q. In the last 1990s, the POPQ scale was adopted by the International Incontinence Society; correct?

A. Yes.

Q. And that brought with it a standardized way of measuring prolapse for the first time.

A. Correct.

Q. And since that time surgeons in clinical studies have used the POPQ scale to assess prolapse; correct?

A. Some have, yes.

Q. Sacrocolpopexy, does it have a risk of rectal injury?

A. Theoretically, yes.

Q. Has rectal injury been reported in any clinical studies that you're aware of with regard to sacrocolpopexy?

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A. I suspect it probably has.

Q. When you say theoretical, what do you mean by that term?

A. Well, the rectum is actually quite a ways away from the vagina when you're doing your dissection. It is -- it's not close. The bladder is close and adherent but the rectum is a long ways away, unless they've had some type of previous operations and it will be scarred in. So yes, theoretically, it is a risk.

Q. Okay. I understand.

A. But --

Q. Injury to the bladder is a risk with sacrocolpopexy.

A. Yes.

Q. And that's because of the proximity of the bladder to the planes in the dissection areas for the sacrocolpopexy; correct?

A. Yes. And frequently, that there's previous scar tissue there from previous surgeries. So it's much more stuck.

Q. There's a life-threatening injury

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to the great vessels when you do a sacrocolpopexy; correct?
MR. ANDERSON: Objection.
THE WITNESS: Again, that falls in line with theoretically. The great vessels aren't really where you're working. We have a good amount of distance away from them.
BY MR. SNELL:
Q. Is there a risk of injury to the internal iliac vessel with sacrocolpopexy?
A. Yes, there's going to be a potential risk. Yes. That risk should be very uncommon and remote.
Q. What's a presacral hemorrhage?
A. Presacral is from the presacral vessels on the sacrum itself. So the veins bleed.
Q. So there's a risk of presacral hemorrhage with sacrocolpopexy?
A. Yes. That's been very well described.
Q. And that's because you're attaching part of that mesh up to the sacrum; correct?

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A. No. It's because you've cut into veins that are the presacral veins. So it has nothing necessarily to do with the mesh itself. It's your dissection.
Q. So part of the risk with dissection in a sacrocolpopexy is the risk to cutting into the presacral veins.
A. Yes.
Q. Osteomyelitis has been described as a complication associated with sacrocolpopexy; correct?
A. Yes.
Q. Sacral bone infection --
A. Yes.
Q. -- is a risk with sacrocolpopexy?
A. Yes.
Q. The abdominal sacrocolpopexy is a procedure that can take over three hours; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I can only answer for myself. And it shouldn't. You should be out of there in two hours.
BY MR. SNELL:

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Q. You never had cases where it's taken you more than three hours to perform a sacrocolpopexy? An open abdominal sacrocolpopexy.
A. Yeah, open abdominal.
I may have. I mean, it's within the realm of possibility, but it -- but it should move along.
Q. One of the reasons why you began performing robotic laparoscopic sacrocolpopexies is because of the high degree of morbidity associated with an open abdominal sacrocolpopexy; isn't that correct?
A. Higher degree of morbidity. There's a difference to me.
Q. Were you performing laparoscopic sacrocolpopexy before you began doing robotic laparoscopic sacrocolpopexy?
A. No.
Q. Your first case of robotic laparoscopic sacrocolpopexy was in 2001; correct?
A. I'd have to look at the date on it. I don't recall the manuscript out there

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on it but...
Q. What's your recollection of your first case of robotic sacrocolpopexy?
A. I was thinking it was in 2002, but I don't -- it was in that time frame.
Q. Your first case of robotic sacrocolpopexy took you about four hours and 45 minutes long.
Do you recall ever saying that?
A. Correct. Yeah.
Q. When you first began doing the robotic laparoscopic sacrocolpopexy to treat prolapse, did you use the da Vinci machine?
A. Yes.
Q. Robot?
A. That's the only robot commercially available that I'm familiar with.
Q. So in your first case of robotic sacrocolpopexy in either 2001 or 2002, that was done with the da Vinci robot.
A. Correct.
Q. And all of your subsequent cases of robotic laparoscopic sacrocolpopexy to treat vaginal prolapse have been with the da

Vinci robot?
A. Correct.
Q. And how were you trained on the da Vinci robot?
A. I am not. Dr. Chow, my partner, is. As I mentioned earlier, this is a team. We do this.
Q. How do you -- Dr. Chow?
A. Dr. Chow, C-H-O-W. George Chow.
Q. So when you would do a robotic laparoscopic sacrocolpopexy, it would be you and Dr. George Chow performing the procedure on a patient for prolapse treatment?
A. Correct.
Q. Do you operate the robot?
A. He drives the robot, as we say. He droves the robot. I'm the one actually with the patient directing where Chow -- where dissection goes, sutures go. He is trained in, fellowship trained in robotics, and so we do -- that's why we do it as a team.
Q. So Dr. Chow is -- is he fellowship trained in robotics?
A. Yes. He did his residency at

Cleveland Clinic in urology and fellowship at Hopkins. And his fellowship is specifically robotics. Well, robotics/laparoscopy. It's a combined fellowship.
Q. When you switched from the Gore-Tex mesh to the polypropylene mesh for your sacrocolpopexies, is it correct that you thereafter continued to do open abdominal sacrocolpopexies?
A. Yes. I -- I changed from Gore-Tex to polypropylene prior to us doing it robotically.
Q. So when was the last time you performed an open abdominal sacrocolpopexy?
A. Probably within the last month.
Q. Okay.
A. More or less.
Q. Since 2002, what prolapse surgeries have you done besides open abdominal sacrocolpopexy and the robotic laparoscopic sacrocolpopexy which was done with you and Dr. Chow?
A. Uh-huh. The anterior colporrhaphy, posterior colporrhaphy, Mayo

culdoplasty.
Q. What's the Mayo culdoplasty? How is it different from the McCall's?
A. It's essentially the same thing. It's fixation to the uterosacral ligaments. There's minimal difference between the two. You can call it McCall's culdoplasty. It would be fine.
Q. And do you view the robotic laparoscopic sacrocolpopexy as a minimally invasive prolapse surgery?
A. Comparing it to the open, yes. Minimally invasive is not a defined term so you have to compare it to whatever -- you have to have a frame of reference.
Q. So compared to the open abdominal sacrocolpopexy, it's your opinion that robotic laparoscopic sacrocolpopexy is minimally invasive.
A. Correct.
Q. When you would be using the robotic laparoscopic sacrocolpopexy, would the patient be under general anesthesia?
A. Yes. For the robotic, yes, they would, under general.

Q. There's a higher risk to the patient the longer she is under general anesthesia; correct?
A. Well, you have to define what the risk you're talking about is.
Q. What are the risks, Doctor, with general anesthesia?
A. I think the longer -- well, then general anesthesia in and of itself, MI, embolic event, other cardiac events, prolonged ileus. I mean, those are some of them I can think of just off the top of my head. There's going to be more. You'd have to talk to an anesthesiologist about that.
Q. Embolic, you mean things like PE and DVT?
A. Correct. Thromboembolic event. Yes.
Q. The longer a patient is under general anesthesia, isn't it correct that there is a higher risk of pulmonary embolism?
A. Yes. I would assume so. I have not reviewed the anesthesia data on that, but that's pretty much the dogma out there,

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that the longer you sleep, the more complications.
Q. Is that something that you disagree with?
A. No. I agree with it.
Q. Okay.
A. I have not studied it myself.
Q. And the ileus you identified as what we earlier discussed, the intestinal blockage?
A. Not blockage. Slowed down. There is no blockage. There's a huge difference. It's just that the intestines are somewhat stunned after anesthesia. They take a while to wake up.
Q. In your robotic laparoscopic sacrocolpopexy cases, some of them have taken up to five hours to complete; correct?
A. I'd have to review our data on it. I don't recall.
Q. As you sit here, you don't recall?
A. I don't -- no. I have a paper out, our first 30. I'd have to look at that. But now we're up to 90. So now we're

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routinely around two hours, 2:15. I'm not denying it may have taken five hours. I just don't recall.
Q. When you first began using Gore-Tex during your fellowship for the sacrocolpopexies, did you investigate whether the FDA had cleared it for the treatment of pelvic organ prolapse?
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: No, I -- I assumed the company had done that. I trusted their opinion, if they're providing it for me, that it had been approved.
BY MR. SNELL:
Q. When you first began using the Gore-Tex mesh -- strike that.
During your use of the Gore-Tex mesh in your fellowship to treat sacrocolpopexy, did you read the IFU to check the indications of use?
A. The IFU that was -- yes. The IFU that was provided for us, this was a sheet of Gore-Tex, I don't remember how large, but

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it was like let's just say eight by eight or something like that. It was a sheet. And then the surgeon would cut it out to form whatever shape he needed. And so I do remember he gave it to me, I reviewed it because I was writing up a paper at the time, which is in my CV, about sacrocolpopexy.
Q. Okay.
A. Because I rely on those.
Q. Do you recall what specific Gore-Tex product that was?
A. No. I would be able to track it down on my CV, if I could get ahold of the original manuscript.
Q. I have a copy of your CV here.
A. Uh-huh. 2004.
Q. What paper are we talking about, Doctor?
A. That's what I'm getting to.
MR. ANDERSON: He's looking.
THE WITNESS: Here we go.
Under "Non-peer-reviewed Articles," Elliott Cone, Boone. Mark Cone, that was the name of the GYN I worked with. "Transabdominal

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Sacrocolpopexy for Severe Vaginal Vault Prolapse: Indications and Results," published in "Issues In Incontinence," 2000. Number 1 on the non-peer reviewed.
BY MR. SNELL:
Q. Turn, if you would, to Page 4 of your CV.
A. Okay.
Q. Under "Presentations, International," it says, "Colloquium-ICS/IUGA, 2004, Paris, France," August 2004.
Do you see that?
A. Yes.
Q. Did you attend ICS/IUGA 2004 in Paris, France?
A. Yes.
Q. Did you see any of the presentations there concerning transvaginal mesh?
A. Not that I recall, no.
Q. Did you make any presentations at ICS/IUGA 2004?
A. Yes.
Q. Which one?

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A. I don't know. It doesn't state it there. For some reason, it's not on the CV.
Q. It's not listed anywhere in your CV what presentation you made at ICS/IUGA 2004?
A. No. It was a poster. I know that.
Q. What was it a poster about?
A. That's what I don't know. I know I had that poster because I had to carry it all the way from Minneapolis to Paris, but I don't remember what the subject matter was.
Q. As you sit here today, you don't know whether it was prolapse, urinary incontinence or some other condition that you treated back then at that time?
A. It would have been one of those two because it's essentially a female urology or voiding dysfunction.
Q. Was it a poster in connection with any consulting you were doing at the time?
A. No.
Q. When you first began performing

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robotic laparoscopic sacrocolpopexies, were there any randomized, controlled trials of that procedure?
A. We were the first in the world to do it so it was impossible to have that.
Q. So when you began performing robotic laparoscopic sacrocolpopexies, there were no randomized, controlled trials on that procedure anywhere in the world; correct?
A. That I am familiar with, correct. Yes.
Q. When was the first randomized, controlled clinical trial involving robotic laparoscopic sacrocolpopexy published?
A. I'm not familiar. I don't know.
Q. You don't even know of one that's ever been published; correct?
A. There may have been. I don't know. I'd have to do a literature search.
Q. You've never been involved in a randomized, controlled trial involving the robotic laparoscopic sacrocolpopexy; correct?
A. Correct.

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Q. And since 2001, how many laparoscopic -- strike that.
Since 2001, how many robotic -- God, I can't talk.
MR. ANDERSON: Great commercial.
BY MR. SNELL:
Q. Since 2001, how many robotic laparoscopic sacrocolpopexies have you done?
A. 90.
Q. Let's just finish up with the CV real quick.
The 2000 "Issues in Incontinence" --
A. Uh-huh.
Q. -- non-peer-reviewed article that you identified --
A. Yes.
Q. -- is that something you have with you on a computer or anywhere that's convenient or is that back at your office or what?
A. I don't have any copies, period.
Q. So you've performed 90 robotic laparoscopic sacrocolpopexies since 2001.

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That's less than ten a year; correct?
A. Correct.
MR. SNELL: Let's mark this as the next exhibit.
(Exhibit Elliott-3 was marked for identification.)
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit Number 3.
Do you recognize this as one of the articles that you published on robotic-assisted laparoscopic sacrocolpopexy for the treatment of vaginal vault prolapse?
A. Correct.
Q. This was an article published in 2004; correct?
A. By the copyright date, that's what it says, yes.
Q. And was this one of the publications you earlier referenced in your deposition with regard to some of the early robotic laparoscopic sacrocolpopexy cases you had performed?
A. I was referring to the one with

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30 patients. This is one -- this is our five -- first five. It was a feasibility study. That's why it's in "Surgical Techniques in Urology."
Q. Over on the right-hand column in the paragraph that begins with "Realizing" -- are you with me there?
A. Yes.
Q. You say, "The difficulties in performing the procedure and the duration of the operation has, however, limited its use."
You're referring to the laparoscopic sacrocolpopexy there?
A. That's what it states, yes.
Q. Turn to the next page, Figure 1. This is a picture of the different ports and -- strike that.
Figure 1 is a picture of the different port placements associated with the da Vinci robotic laparoscopic sacrocolpopexy that you were performing?
A. Correct.
Q. And for the robotic laparoscopic sacrocolpopexy, that involves the use of

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trocars; correct?
A. Yes.
Q. What's the largest size trocar used during this robotic laparoscopic sacrocolpopexy?
A. Currently, I don't know because they've decreased in size.
Q. Back then it would have been 12 millimeters --
A. That --
Q. -- to place the camera port?
A. That's correct.
Q. There would be a 10-millimeter trocar; correct?
A. Yes.
Q. A couple 8-millimeter trocars; correct?
A. Yes.
Q. A 5-millimeter trocar port one hand breadth inferior laterally?
A. Yeah, that's what it states. Yes.
Q. A little below that you note that the two 8-millimeter robotic ports are placed lateral to the rectus; correct?

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A. Well, it states, 8-millimeter robotic ports placed at inferior lateral rectus. So that's --
Q. I'm sorry. We must be at the wrong --
A. I'm still on Figure 1.
Q. Okay.
A. That's what it describes there.
Q. I'm in the text now at the bottom of Page 374, the last sentence in the first column.
A. Yeah. Two 8-millimeter robotic ports are placed lateral to the rectus two finger breadths superior to the iliac crest.
Q. And when you use the term "two finger breadths," that's a term that's been used in your medical training; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Well, two finger breadths is just a -- a rough estimate. In subsequent papers we actually use centimeters. But in here it does say two finger breadths.
BY MR. SNELL:

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Q. In your first description of your use of the da Vinci robot to do prolapse surgery you described the distance in finger breadths.
A. Correct.
Q. Figure 3 is a -- says, "Silastic Y-graft"; correct?
A. Yes.
Q. Is this the AMS graft that you earlier identified or is this the Gore-Tex graft?
A. No, this is not -- this is the one in between the Gore-Tex and then the AMS polypropylene. And then it says here, "Silastic Y-graft." We used this only a very short period of time.
Q. So tell me about this Silastic Y graft. What kind of graft is that?
A. I -- well, it says, "Silastic Y-graft." That's about all I know because I don't -- I don't recall. Usually in the manuscripts we put in who makes it and things. We didn't do it in this.
Q. Take a look and you tell me.
A. Well, on quick review I don't see

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any indication of a manufacturer.
Q. Well, what's your understanding of what type of material a Silastic graft is?
A. Well, Silastic is Silastic. I don't -- I don't know anything else beyond that.
Q. Is it mono-filament, multi-filament?
A. I don't know.
Q. Is it macro-porous or micro-porous?
MR. ANDERSON: Objection.
THE WITNESS: Yeah. I'm not a biomaterials expert, and I'd have to look at it and measure it and things.
BY MR. SNELL:
Q. Is it a synthetic material?
A. Yes.
Q. The Silastic grafts that you were using for prolapse, do you know if they were FDA approved for the treatment of prolapse?
A. Well, since it was provided to me by a company, I don't know what, I'm going to assume it is.

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Q. I'm not asking what you assumed. I'm asking if you know.
Do you know, Doctor, whether the Silastic grafts you used in patients in your first robotic sacrocolpopexy series were FDA-cleared for the treatment of pelvic organ prolapse?
A. I'm going to trust the company and say yes, it is.
Q. What's the name of this company?
A. That's what I don't know.
Q. I'm not asking you to trust the company. I want to know, when you were placing this Silastic graft in patients in this sacrocolpopexy series, was that specific material FDA-cleared for the use of prolapse?
MR. ANDERSON: Objection. Asked and answered a couple different times.
MR. SNELL: I'm not asking what he suspects about a company. I'm saying, what did you know?
MR. ANDERSON: I --
BY MR. SNELL:
Q. Did you know whether it was or

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not?
MR. ANDERSON: Objection. Same objection. Asked and answered.
You may answer it one more time.
THE WITNESS: I assumed since it's a Y-shaped mesh specifically for sacrocolpopexy and no other indication for use that it would be -- gone through the appropriate channels of being approved for use.
BY MR. SNELL:
Q. So you assumed.
A. Correct.
MR. ANDERSON: Asked and answered.
BY MR. SNELL:
Q. But you do not know; correct?
A. No. I tend to trust the companies.
Q. Over on the right side --
A. Page 375?
Q. Correct.
It says your operative -- your average operative time was 3 hours, 42

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minutes; correct?
A. Yes.
Q. With a median of 3 hours, 30 minutes; correct?
A. Yes.
Q. Average follow-up was four months in this publication; correct?
A. Correct.
Q. A little bit further down in the Comment section you talk about the placement in a non-invasive fashion while avoiding a midline abdominal incision; correct?
A. I have to find out where you are.
Q. First paragraph.
MR. ANDERSON: I think it's, "The advantage of."
THE WITNESS: Oh. "The advantage of using a robotic."
Yeah, I see where it says that. Yes.
BY MR. SNELL:
Q. The midline abdominal incision, am I correct that there can be herniation at the site of that incision following an open abdominal sacrocolpopexy?

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A. Yes.
Q. Is that what you were referring to there in that particular sentence?
A. I wasn't referring to -- I was referring to everything entailed in doing a midline lower abdominal incision, so not just limiting it to hernia.
(Exhibit Elliott-4 was marked for identification.)
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit Number 4.
This is another publication in which you are one of the authors from 2004; correct?
A. Yes.
Q. Concerning the gynecologic use of robotically assisted laparoscopy, colon, sacrocolpopexy for the treatment of high-grade vaginal vault prolapse; correct?
A. Yes.
Q. This is in the "American Journal of Surgery"; correct?
A. Yes.
Q. And this is a series of 20

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patients; correct?
A. Yes.
Q. Who had undergone robotic-assisted laparoscopic sacrocolpopexy at the Mayo Clinic in the past 18 months; correct? I'm looking at the abstract. I'm not trying to trick you at all.
A. I'm trying to find it.
Q. Total of 20 patients?
A. Yeah, I see the 20 patients at our institution, past 18 months. Yes.
Q. So the answer to my question is yes?
A. Yes, it is.
Q. And under the "Surgical technique," this was using that same da Vinci Surgical System; correct?
A. Yes.
Q. By the way, back in 2004 how much did that da Vinci Surgical System cost?
A. I don't know.
Q. You know it cost over a million dollars; correct?
A. I just said I don't know.
Q. You've never heard or seen in the

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literature that the cost of a da Vinci Surgical System is over a million dollars.
A. Well, actually, at Mayo they were given to me, so they were free.
Q. For other institutions that aren't so fortunate as the Mayo Clinic to get free things given to them have you seen in the literature that it may cost over a million dollars for the da Vinci Surgical System?
MR. ANDERSON: Objection.
THE WITNESS: No, I have not.
BY MR. SNELL:
Q. How did the Mayo Clinic come to get these da Vinci Surgical Systems --
A. I don't know.
Q. -- for free?
A. I don't know.
Q. How do you know they were given to the Mayo Clinic?
A. That's what I heard.
Q. Who did you hear it from?
A. Chairman of my department.
Q. Chairman of surgery or --
A. Urology.

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Q. Urology?
Figure 1 is a similar figure to what we looked at in your earlier papers showing the different port placements; correct?
A. It is the same picture.
Q. Whose hand is that demonstrating?
A. Mine. At least, I assume it's mine. That's where I stand so...
Q. Who placed the ports when you do this procedure?
A. Dr. Chow.
Q. Who places the trocars first?
A. Dr. Chow.
Q. Now, in these 20 patients there is a Y-sling silicone mesh that was placed?
A. Correct.
Q. Is this the same mesh that we saw in the initial case series of five patients?
A. Yes.
Q. Was this mesh recut by whoever supplied it or did the surgeon team cut the mesh?
A. It comes like this. This picture is what's right out of the box.

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Q. So the Silastic Y-graft and the silicone Y-sling are both the exact same thing.
A. Correct. Yes.
Q. In this group of 20 patients there were some complications identified on Page 54-S; correct?
A. 54-S.
MR. ANDERSON: 54. This one right here, I think.
BY MR. SNELL:
Q. Let me just ask a question.
A. Oh. Sorry.
Q. There were some complications reported in your paper; correct?
A. Yes.
Q. They included mild port site infections in two patients; correct?
A. Yes.
Q. You had a patient who developed a recurrent grade-three rectocele; correct?
A. Yes.
Q. Another patient developed a small erosion six months after the procedure?
A. Yes.

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Q. Correct?
That was managed with outpatient transvaginal excision; correct?
A. Yes.
Q. Significant incontinence was present in 2 of your 20 patients; correct?
A. Correct.
Q. Turn to the next page.
A. (Witness complies.)
Q. Does this refresh your recollection as to what the purchase cost of a da Vinci Surgical System is --
A. Yes.
Q. -- that you put in your paper?
A. Yep.
Q. And what is it?
A. $1 million.
Q. And in many facilities the cost is prohibitive; correct?
A. I -- I -- I can't agree with that, actually, no.
Q. Well, you wrote, Doctor, "Although it is true that the device reduces operative time, for many facilities the cost is prohibitive"; correct?

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A. Uh-huh. That was in 2004, when I wrote it. We're talking now 2012.
Many facilities, if they do not have a robot, will not find themselves competitive so many hospitals, even small ones, are buying these. Specifically in Minnesota, there are hospitals much smaller than Mayo who have more robots than Mayo because it's a competition issue. It doesn't mean that competition is right, but it happens.
Q. The trocars with the da Vinci robotic system, am I correct that they are designed to stop functioning after ten uses?
A. I don't -- I don't know on that because I'm not a robot expert, but there is -- there is a life expectancy to the actual arms, you know. I don't know what the number is, though.
Q. Do you know if there are chips in these robots that program them to shut down after a certain number of uses?
A. Yes, I do know that.
Q. How many?
A. I don't know.

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Q. The series, Doctor, you mentioned earlier, was it 30 cases or --
A. I believe 30, yes.
Q. Can you point me to the publication in your CV? Maybe that will help me find it and we can discuss it. Did you give it back to me?
A. Yeah. I believe it's --
MR. ANDERSON: Let's see if it's here. Yeah.
THE WITNESS: It might be 28 or -- Number 28, 29, because I -- because I'm continually evolving.
MR. SNELL: Okay.
THE WITNESS: I'd have to -- see, there's another one, Number 42. So I don't know which one it is. Because each one, we're reviewing the same patients and following them longer.
(Exhibit Elliott-5 was marked for identification.)
THE WITNESS: Oh, that's 30 patients. This is the one.
MR. SNELL: Okay.
BY MR. SNELL:

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Q. So, Doctor, you've been given Exhibit Number 5; correct?
A. Correct.
Q. This is a paper in which you're one of the co-authors. The title is "Long-Term Results of Robotic Assisted Laparoscopic Sacrocolpopexy for the Treatment of High Grade Vaginal Vault Prolapse"?
A. That is correct.
Q. And it looks like this was published August 2006 in the Journal of Urology; correct?
A. Journal of Urology, 2006, yes.
Q. And was this the paper in which you referred to the 30-patient cohort?
A. Yes.
Q. Doctor, the two articles we looked at that you are a co-author in from 2004 involved 5 patients and then 20 patients, they all involved this silicone mesh; correct?
A. Correct.
Q. Now, this paper has a photo at Figure 3 of a polypropylene Y-graft;

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correct?
A. That is correct.
Q. Is this a different cohort of patients?
A. No. It's both. It's included -- it's the entire series. At some point in time we changed over to using this new mesh.
Q. So you did at least 20 cases with the silicone mesh; correct?
A. I would have to -- whatever -- yeah. I know -- I remember, recall. It was 20 patients on that. So I would assume we used the same silicone mesh on all those.
Q. And at most, this would be 10 new patients with polypropylene mesh.
A. Yes. Apparently so, yes.
Q. Figure 1, the laparoscopic port placement, is this the same photo that we saw in the earlier two publications from 2004?
A. Yes.
Q. What is shown in Figure 2?
A. It's a hand-held retractor that's used, that I am actually the one holding at the time of surgery to help facilitate the

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dissection and placement of the sutures. It's placed into the vagina.
Q. How is this used?
A. The patient is --
Q. Strike that. Let me ask an intelligible question that makes sense on the record.
How is this hand-held vaginal retractor used, as depicted in Figure 3 of your --
A. Figure 2.
Q. I'm sorry. Let me try it again.
How is this hand-held vaginal retractor used, which is depicted in Figure 2 of your 2006 publication, Doctor?
A. The patient is in lithotomy position, which means she's on her back with legs in stirrups. The robot is then placed between the legs.
This vaginal retractor is, as it says, hand-held, where I am holding it and elevating, retracting, moving the vagina various different directions to aid in the robot's dissection and suture placement. So we're able to do more precise, under direct

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vision exactly where we want our sutures to go.
Q. So this is inserted into the vagina.
A. Correct.
Q. The robot does the dissection then.
A. Correct.
Q. Turn to the next page, 658.
So two patients in this series have developed small vaginal extrusions of mesh; correct?
A. Yes.
Q. Each extrusion developed six months following the procedure; correct?
A. Yes.
Q. And they were managed with transvaginal excision and primary closure; correct?
A. Yes.
Q. Now, by this time in August 2006, had any randomized, controlled trials been done on the robotic laparoscopic sacrocolpopexy?
A. I am unaware of any.

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MR. SNELL: We've been going for a while. Why don't we take a little break.
MR. ANDERSON: Okay.
(Recess, 3:04-3:20 p.m.)
BY MR. SNELL:
Q. Doctor, I wanted to circle back around.
Do you have Exhibit 4 handy?
A. Yes, I do.
MR. ANDERSON: Let me hold that for you.
THE WITNESS: Yes, I have it.
BY MR. SNELL:
Q. Under the "Surgical technique" --
A. Okay.
Q. -- on the right side you talk about patients placed in the dorsal lithotomy position.
Do you see where I'm at?
A. Second or first full paragraph, yes.
Q. Yeah. Next paragraph, it says that abdominal insufflation is performed using a varus needle; correct?

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A. Yes.
Q. That's where a needle is placed through the abdomen to --
A. Well, not through.
Q. -- separate the space?
A. Not through the abdomen. Into the abdomen.
Q. Into the abdomen. And it's to separate the space.
A. Well, it's to fill it with air or CO2, yes.
Q. Let's see if we can break that down.
A needle is placed into the abdomen; correct?
A. Correct.
Q. Varus needle, is that a particular type of needle or is that --
A. Yeah, it's a specific type of needle. I don't know what gauge it is. It's a little bit larger, to allow -- roughly, it's about 8 centimeters long, to allow the air to get in or the CO2 to get access into the abdomen.
Q. And the CO2 is placed through the

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needle into the abdomen.
A. Correct.
Q. And that separates the space.
A. Well, not separates it. It fills it with CO2 so you can see inside. I mean, technically, yes, separates. Yeah.
Q. And the abdominal insufflation using this varus needle is performed blindly; correct?
A. Yes.
Q. And there can be injury with abdominal insufflation using a varus needle; correct?
A. Yes.
Q. And this was known to you back in 2004, when you were performing this part of the procedure; correct?
A. Yes.
Q. As a surgeon, were you trained to use your hands and palpate during surgery?
A. That would be part of it, yes.
Q. That's how you were trained; correct?
A. Well, no. I mean, I was also trained to hold instruments and tie knots

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so --
Q. I'm not saying that's the entirety of how you were trained.
A. Well, palpate what?
Q. When you were performing surgical procedures, were you trained to palpate during those procedures to aid you?
A. Well, "palpate" is not a word I use.
You use all the senses given to you -- not all of them, majority of them -- to perform the surgery appropriately. So the tactile feedback and feeling is one of them. I'd prefer to use that as opposed to palpate.
Q. So the tactile feeling and feedback is one of the modes in which you were trained on as a surgeon.
A. Correct.
Q. And you would agree that injury can occur during a surgery, even under direct visualization.
A. Yes.
MR. SNELL: Let's mark another exhibit.

(Exhibit Elliott-6 was marked for identification.)
BY MR. SNELL:
Q. Doctor, you mentioned studies that you have been involved in on rabbits and different types of materials, autologous materials, polypropylene.
Was this one of the studies you were referring to?
A. Yes.
Q. And this was a study that was published in 2004; correct? May 2004; right?
A. May 2004. You are correct.
Q. It was a study in 15 rabbits, white New Zealand rabbits, I believe?
A. New Zealand -- yes, 15 rabbits.
Q. And what you did was each rabbit was implanted with different materials; correct?
A. Yes.
Q. Human cadaveric fascia, porcine dermis, porcine small intestine, submucosa, polypropylene mesh and autologous fascia; correct?

A. Yes.
Q. And that was implanted along the anterior rectus fascia; correct?
A. Yes.
Q. Figure 1 has a depiction of the actual different materials as implanted; correct?
A. That is correct.
Q. And you wanted to investigate time-dependent variations in tensile strength, stiffness, shrinkage, and distortion; correct?
A. Yes.
Q. In six materials commonly used for transvaginal anti-incontinence surgery; correct?
A. Yes.
Q. So shrinkage is one of the things you looked at in 2004; right?
A. I'm just reviewing the paper.
Q. First line under "Purpose."
A. "Purpose." Shrinkage, yes.
Q. So you looked at the degree of shrinkage with these different materials, including polypropylene mesh, in 2004;

correct?
A. That is correct.
Q. You earlier mentioned -- strike that.
You earlier referenced that fibrosis was later recognized to be shrinkage.
Do you recall, in general, your testimony?
A. I remember mentioning something along that lines, yes.
Q. Just so -- and you -- and I believe you testified you thought you later came to learn that?
A. Yeah. When we're looking at shrinkage in this manuscript, we're focusing mainly on autologous and cadaveric tissues, and then what I was referencing in the deposition was the increased fibrosis, as we mentioned in here, and we're looking -- because this is 2003 when the study was done.
Q. Right.
A. Or actually it was started in 2002.

Looking back now, that increased fibrosis we would say would be leading to contraction and shrinkage.
Q. Just so I'm clear, this study was completed in 2003; correct?
A. Yes.
Q. And it included shrinkage of the mesh in it; right?
A. Yes, that is one of the factors. Yes.
Q. In fact, if you turn to Figure 3, of the different materials where you assessed the percent reduction in surface area --
A. Uh-huh.
Q. And that's shrinkage; correct?
A. Yes.
Q. -- the polypropylene mesh had the lowest percent reduction of surface area of any of the materials you studied; correct?
A. That is correct. Which is known by Johnson & Johnson. I found this paper in their internal documents referencing it.
Q. Besides your paper in 2003, mesh contraction had been reported in the

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literature long before that time; correct?
A. I suppose so, yes. I don't know.
Q. The human cadaveric fascia and porcine allografts showed marked decrease in tensile strength; correct?
A. Again, I'd have to go back and look at the paper. Off the top of my head --
Q. I'm right there, right in the "Results."
MR. ANDERSON: He's looking at --
THE WITNESS: Yes.
BY MR. SNELL:
Q. And they had marked decrease in stiffness from baseline; correct?
A. Yes.
Q. Polypropylene mesh and autologous fascia did not differ in tensile strength from baseline; correct?
A. Yes.
Q. Polypropylene mesh increased in stiffness from baseline; correct?
A. Yes.
Q. The autologous fascia and small

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intestinal submucosa demonstrated a 41 percent and 50 percent decrease in surface area respectively at 12 weeks.
A. I'm sorry. I lost where you are.
Q. Right there on the "Results" section of the abstract of your paper in 2003.
MR. ANDERSON: Well, he's just trying to get to the point where you're reading from.
THE WITNESS: Okay. I heard what you had to say. I just wanted to know where we are. Page 1971, second column.
BY MR. SNELL:
Q. "Results."
A. "Results."
Q. At the very front. No. No. I'm sorry. Doctor. In the very front, in the "Abstract."
A. Oh, in the "Abstract." Okay.
Q. So you were looking at the "Results" section.
A. Yes.
Q. I was looking at the "Results" part of the abstract. I see. No problem.

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"Autologous fascia and small intestinal submucosa demonstrated a 41% and 50% decrease in surface area, respectively, at 12 weeks"; correct?
A. Yes. Correct.
Q. On Page 1970 on the right-hand column. I'm going to show you where I'm looking, Doctor?
A. Yes. I saw it highlighted.
Q. "Polypropylene mesh slings can typically be placed in an outpatient setting."
So you wrote that?
A. Yes.
Q. That's consistent with your clinical practice as well; correct?
A. Correct.
Q. In fact, you've said that placement of these slings can be performed in about 15 minutes; correct?
A. 15 to 20, yes.
Q. But they have a finite risk of erosion, extrusion and infection; correct?
A. Yes.
Q. You were aware of the risk of

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mesh erosion in 2003 when you wrote this paper; correct?
A. Yes.
Q. You were aware of the risk of mesh extrusion in 2003 when you wrote this paper; correct?
A. Yes. In the -- in the setting of slings, yes, which is a very important aspect of that.
Q. Towards the end of your paper --
A. Okay.
Q. -- second-to-last paragraph, you say, "Recent studies showed higher than expected intermediate failure rates for cadaveric fascia lata slings"?
A. Yes.
Q. Is that some of the data which you were earlier referring to when you discussed your preference to use synthetic slings over autologous and cadaveric slings?
A. No. What I was referring to was Brubaker's paper on sacrocolpopexy specifically. So, no, I was not -- was not referencing this.
Q. You say, "processed cadaveric

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fascia lata grafts have been shown to retain antigenicity."
A. Uh-huh.
Q. Did I --
A. Yeah.
Q. -- pronounce it correctly?
A. Yeah. Pretty good.
Q. What is that, Doctor?
A. That just means that -- you know, I'm not an immunologist so I'll give an infantile answer for it. It is that the theoretical possibility that fascia lata from a cadaver can still retain some of its antigens, so that the body views it as not them.
Q. And in the literature that's been discussed in the context of patients who rejects cadaveric slings.
A. Not reject. They're worried about the long-term, 20-, 30-, 40-year history with prions, P-R-I-O-N-S, and the potential transmission of disease processes such as Creutzfeldt-Jakob. There's several of those names. But no, we're not worried about rejection necessarily. No, actually

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not at all. It's infectious transmission.
Q. So the concern with cadaveric fascia lata grafts in this context that you wrote in 2003 pertained to the transmission of infection.
A. Correct. That's specifically antigenicity, which you pronounced better than I just did, is pertaining to that infectious transmission long term.
Q. At the end of that paragraph you say, "The biomechanical results of the current study support the use of polypropylene mesh for sling surgery relative to other nonautologous materials"; correct?
A. Yes.
(Exhibit Elliott-7 was marked for identification.)
BY MR. SNELL:
Q. All right. Doctor, I've handed you Exhibit Number 7, which is another paper in which you are a co-author on from 2006 --
A. Yes, I have it.
Q. -- in the Journal of Urology; correct?

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A. Yes.
Q. And this was a study that you completed in 2005; correct?
A. Well, no. The paper was finished in 2005 so I don't know, actually, when the study was completed. It would have been in that time frame, 2004, 2005.
Q. And this was another study in rabbits?
A. Correct. Same kind of rabbits, New Zealand rabbits, I believe.
Q. And one of the things you looked at in this study was inflammation associated with the different implants; correct?
A. Yes.
Q. And of the different materials, polypropylene mesh had the lowest degree of inflammation; correct?
A. That's what we found at our 12-week study, yes.
Q. Did you ever do a follow-up study to this longer-term data that showed something different than that?
A. No. No.
Q. Whenever you do a surgery,

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Doctor, any kind of surgery, and you make incisions, the body's natural response is to try to heal; correct?
A. Yes.
Q. Setting aside cases where somebody is, you know, highly immunosuppressed, in general, we can agree that the body normally tries to heal.
A. Yes.
Q. And for a surgery involving basic incisions, the body's natural response is to try to heal that area and form a scar; correct?
A. I don't know what you mean by the basic incisions.
Q. If an incision is made on your arm during surgery to place pins in one of the bones, the body's natural response is to try to heal that incision area and form a scar; correct?
A. The body -- the body -- the goal of the body is to heal itself, yes. Correct.
Q. And scar formation is the way that the body heals itself.

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A. I --
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Yes. But in your example, putting the pins in the body, now you've got a foreign body reaction. So now the body might not be able to heal itself or it may go into overdrive and attempt to heal itself and now you have a -- a poor environment for healing.
BY MR. SNELL:
Q. You know pins have been used in orthopedic surgeries for decades?
A. I -- I assume so. I don't know. Because I'm not an orthopedic surgeon.
Q. Explain to me the process, then, Doctor, by which the body heals itself when you have something like an incision and you put stitches in the incision. How does the body go about healing itself?
A. It is an incredibly complicated and still to this date poorly understood process. Myself as a urologist are not going to understand all the nuances. Actually, it gets into immunology.

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There is a whole cascade of events that happens as soon as there is a break in the skin and blood is spilled because that sets off this cascade, which I'm not, by no means, am going to be an expert on. But then that sets off platelets, it sets off the immune response, neutrophils, which incorporate macrophages.
It is an amazingly complicated and incredible cascade of events. Anything that inhibits that, whether it be a pin in the arm, which can get infected or create any type of foreign body response or infection, will -- can inhibit that proper cascade.
Q. How large are neutrophils?
A. That is a question that is still evolving. Again, I'm not an immunologist; however, it depends upon what type of neutrophils you're talking about because neutrophils are different throughout the body. Are you talking in the lung? Are you talking in the pelvis? All the --
Q. Let's talk about neutrophils in the pelvis, neutrophils that are involved in

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the body's tissue integration with regard to pelvic mesh.
A. Okay. Now then I'll have to ask more questions. Is this when these neutrophils are at rest, so to speak, or are these neutrophils, once they have been activated and are starting to be involved in phagocytosis and moving around and picking up debris? Because neutrophils, i.e., macrophages, gobble up -- again, that's not a good academic term, but they -- they incorporate debris. So they can become very large. So I cannot give you --
Q. Before they incorporate debris.
A. I would say you can have a range of 20 to 80 microns.
Q. So just so I have this correct, neutrophils before they gobble up anything can be up to the size of 80 microns.
A. I've seen reports with macrophages up to 4,000 microns.
Q. Macrophages, yeah. I want to talk about --
A. Well, but that's a subset.
Q. Okay.

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A. I think the immune system is insanely complicated. There's no lawyer in this room who understands them. I am a surgeon who has been studying it. I don't understand it. And immunologists are just beginning to understand it. Okay.
So I can give you a preliminary explanation, actually, from what I've read. But, yes, alveolar macrophages, 4,000 microns is in the data out there.
So when you say neutrophils, you are actually by default saying macrophages because that is a subset.
Q. So are alveolar macrophages involved in tissue integration with mesh?
A. They sure can be.
Q. I'm not talking about can be. I'm asking, are they? I want to know, are they?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Well, I just answered that. See, the -- what I can -- I can be a smart aleck and say, do you know what alveolar macrophages are?

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BY MR. SNELL:
Q. No.
A. The answer is going to be no.
Q. But I'm not the doctor.
A. But if you have thoracic wall hernias that are repaired, then the alveolar macrophages can be involved in that, yes.
Q. I thought we were talking about for prolapse.
A. Read your question.
MR. ANDERSON: But you changed it to mesh and that's why he was having a problem when you just said mesh.
See? Alveolar macrophages involved in tissue integration with mesh is what you said.
MR. SNELL: Okay.
BY MR. SNELL:
Q. Are alveolar --
A. Alveolar.
Q. -- alveolar macrophages involved in tissue integration with the mesh used in pelvic organ prolapse?
A. Well, the mesh used in pelvic organ prolapse can also be used up in

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thoracic wall hernias.
Q. But I'm not talking about thoracic wall hernias right now.
A. I'm sorry. But I was answering your question.
If you want to be specific in the mesh, that is used for the purpose of healing pelvic organ prolapse. Alveolar macrophages are not in that.
Q. Have you seen it reported in the medical literature that macrophages that are associated with tissue integration for mesh in pelvic organ prolapse are approximately 20 to 30 microns in size?
A. Well, that goes back to my answer. I said 20 up to 80. And I am not an expert in this. I'm just saying what I have read in the work of others.
Q. What type of neutrophils or macrophages involved in the tissue response for mesh for pelvic organ prolapse are between 50 and 80 microns?
MR. ANDERSON: I'm going to object.
He's not being offered as an

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expert in the area of immunology or pathology or pathophysiology. So with those objections in mind, if you want to continue asking questions, I'm going to continue objecting, but he's not being offered as an expert witness on this.
BY MR. SNELL:
Q. You mentioned up to 80. I just want to know which ones are between let's say 50 and 80.
MR. ANDERSON: Same objection applies to that so --
THE WITNESS: The subset, I'm not familiar with the name of the subset.
MR. SNELL: Okay.
BY MR. SNELL:
Q. Figure 3 in this paper shows a comparison of the different degrees of inflammation between the polypropylene mesh, which is on the left; correct?
A. Yes.
Q. And the two different cadaveric fascia latas at 12 weeks?
A. Yes.
Q. Were you involved in the taking

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of these photographs?
A. No. That would have been the pathologist. I believe it was Tom Sebo.
Q. Do you know at what power those photographs were taken? I didn't see it in here.
MR. ANDERSON: Objection.
He just said he wasn't involved in it.
MR. SNELL: I'm just asking if he knows from the paper. I didn't see it in the paper, the magnification, but I want to know if he has a recollection or a knowledge that I, obviously, I don't know.
THE WITNESS: I have no recollection. I'd have to go to where I'm describing Figure 3 and say if we describe it.
MR. SNELL: Figure 2. I'm sorry.
THE WITNESS: Oh, Figure 2.
MR. SNELL: Oh, no. You're right, Doctor. Figure 3. Figure 3. You're right. I misspoke.
THE WITNESS: I don't see

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Figure -- where I'm just talking about Figure 3.

MR. ANDERSON: That's all right.

There's not a question pending; right? Because he said I don't see it. You asked him if he saw the magnification and he said I don't see it.

THE WITNESS: I'm sorry. I said I don't see it.

MR. SNELL: Okay. I didn't hear you. I thought you were just looking for the reference to Figure 3.

THE WITNESS: I --

MR. ANDERSON: Off the record.

(Discussion off the record.)

BY MR. SNELL:

Q. At the last page, Doctor, under "As alternatives," looking at the bottom left corner --

A. I see it, yes.

Q. So that in this paragraph you're talking about the use of polypropylene mesh; correct?

A. In the setting for mid-urethral

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slings, yes.

Q. Correct.

And you say, "Our results indicated little degree of inflammation"; correct?

A. Yes.

Q. "And significant fibrosis"; correct?

A. Yes.

Q. "Similar to that of autologous material"; correct?

A. Yes.

Q. Moving a little further, you also note, none of the material appeared grossly infected at explantation in your study; correct?

A. Yes.

Q. In this paper you talk about some of the limitations of your study; correct?

A. Yes.

Q. One of it is that you used an animal model; correct?

A. Yes.

Q. And there's differences between humans and animals, obviously; correct?

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A. Yes.

Q. There's differences in studies that seek to look at clinical conditions in humans and compare those with animal models; correct?

A. Yes.

Q. Towards the end you note in the "Conclusions" section, "These results add additional objective evidence to distinguish the different synthetic materials used in anti-incontinence surgery"; correct?

A. Yes. I mentioned that in the "Conclusions" section and also warn of the differences in the microenvironment of the vagina and infection. So yes, it has to be taken in its totality, these conclusions, so you have to --

Q. Right.

A. But yes, that's the -- my statement that you said, that's what I state here.

Q. The slings that you use transvaginally, the synthetic polypropylene slings, have you published on your infection rate with those slings?

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A. I do not believe I have.

Q. As you sit here today, what is your infection rate for your polypropylene slings?

A. Are you talking about vaginal extrusion or infection of the mesh? Because there's a -- like I said, I just want clarification of what you're asking.

Q. Infection with the mesh.

A. One out of 1,500.

Q. So one out of 1,500 --

A. That I know of. I'm sorry to interrupt you.

Q. That's okay.

A. You have to put that preface in there, that I know of, one out of 1,500.

Q. I don't want you to testify about things you don't know about. So one out of 1,500 polypropylene slings that you've placed, that you're aware of, has become infected.

A. Correct. And required explant, yes.

And let me actually be more clear on this one also because I -- in

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making that statement, I excluded the OB tape. Our series of OB tapes, which are no longer on the market, we had 8 out of 100 become infected, very significant, severe infections. Okay. So when I -- I gave that number, I actually should preface by excluding OB Tape.
Q. Well, the 1,500 slings that you identified, you have one mesh infection out of, let's just focus on that one.
A. Correct.
Q. That's a macroporous sling; correct?
A. It's the SPARC suburethral sling, so I don't know as far as the macroporous. It's --
Q. Do you know if it's a larger pore size than the OB Tape?
A. Yes, definitely, it is.
Q. Do you know how that pour size of the SPARC tape compares to the pour size of the mesh used with, say, TVT®-O?
A. All I would be able to do is not on a scientific level, of saying just eyeballing it, for lack of a better phrase,

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eyeballing it, they appear to be very similar.
Q. Now, you also mentioned extrusion --
A. Extrusion.
Q. -- when you were asking me for clarification?
A. Yes.
Q. In these 1,500 polypropylene slings, can you tell me what your extrusion rate was?
A. Excluding the OB Tape.
Q. Let's just set that aside.
A. It's two that I know of.
Q. Two of 1,500?
A. Correct.
Q. Have you ever published on the rate of mesh exposure or extrusion in the abdominal sacrocolpopexies that you have done?
A. We have not published specifically on it; however, it is referenced in the manuscripts.
Q. Sorry. My question was about the abdominal sacrocolpopexies.

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A. Oh, sorry.
Q. Let me just check my question and make sure that was what I thought.
MR. ANDERSON: You were right.
THE WITNESS: Yeah. I misunderstood your question. I'm sorry.
MR. SNELL: That's okay.
BY MR. SNELL:
Q. Let me just ask, have you ever published on the rate of mesh exposure or extrusion in the abdominal sacrocolpopexies that you have done?
A. No, I have not.
Q. Do you know the rate of mesh exposure for the abdominal sacrocolpopexies that you have performed?
Well, let me back up, actually. Maybe you told me this before, and if you did, I apologize, because I've forgotten, clearly.
How many abdominal sacrocolpopexies have you performed over your career?
A. Roughly, we're looking at, what, 14 years now, 100, 150. Something like

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that.
Q. Have you ever published on your experience in abdominal sacrocolpopexy?
A. No.
Q. Have you ever presented on your experience with abdominal sacrocolpopexy with like a poster or, you know, a meeting, anything like that?
A. No.
Q. Are there any studies or publications or presentations that you have been involved with which concern the use of mesh to treat either stress urinary incontinence or prolapse that are not included in your CV?
MR. ANDERSON: Objection.
MR. SNELL: Can you tell me what's wrong, Counsel? I just want to --
MR. ANDERSON: That he's been involved with. I don't know --
MR. SNELL: Okay. That's fair. That's fair.
BY MR. SNELL:
Q. Are there any studies or publications or presentations that you have

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been a co-author on or the presenter on that concern the use of mesh to treat urinary incontinence or prolapse that are not identified in your CV?

A. No. Specifically, to answer your question, no; however, we have submitted for meetings, like the SUFU meeting in February, robotic sacrocolpopexy in obese patients, and so -- but that has not been presented.

Q. Got you.

A. And then we will be submitting to the AUA that manuscript and then the other one is artificial -- so no, that would be -- there is no publication pending out there that I'm aware of off the top of my head other than those two presentations.

Q. And both of those involved robotic sacrocolpopexy in an obese cohort?

A. Correct.

Q. How large of a series is this obese cohort?

A. I believe it's involving all of our 90 patients.

Q. Were all of the 90 patients obese?

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A. No. What we're doing is we're comparing moderate -- normal BMI to enlarged, elevated BMI.

Q. So is it normal BMI as compared to overweight and obese, as defined by the BMI scale, CDC, or normal weight versus obese BMI of 30 or above?

A. Your first statement, that we are comparing the various BMIs, so we have --

Q. Okay.

A. -- normal, mildly elevated and then morbidly obese.

Q. Is this a retrospective cohort study?

A. Yes.

Q. So within the 90 patients for whom you have been involved with robotic laparoscopic sacrocolpopexy, that's the cohort and it's just stratified by BMI category.

A. Correct.

Q. Were there any findings that you considered significant or specific -- strike that.

Were there any findings in this

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study which you considered to be specific to the use of mesh?

A. No. It would be specific to obesity and its impact upon robotic sacrocolpopexy.

Q. What effect, if any, did the obesity have?

A. The very impressive data that the larger an individual is as far as obese, the complications increased. There's almost a linear one-to-one association as far as that.

Q. Any particular type of complications or just overall?

A. Overall, and wound infection, delayed hospital stay, increased risk for bleeding and also longer procedure.

Q. Do you know why there was an increased risk of wound infection with the obese cohort?

A. Basically, there's a lot of fat. The more fat -- fat does not heal well at all. So that goes for plastic surgery, general surgery, and this robotics.

That would have surprised us

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somewhat because we felt that robotics would actually reduce that, but still it was reduced compared to open but still significant increased risk compared to thin. Thin is easy, obese is difficult.

Q. And the obese cohort had a longer procedure time, in general?

A. Slightly. Yeah, it was 20 to 30 minutes longer.

Q. Any difference in the rate of mesh exposure or extrusion?

A. We haven't had any beyond our first eight patients. Our first eight patients, which is described in that study of 30, we had, I believe, two and I think we had one after that, a total of three patients with mesh extrusion, which were all in the first eight or nine, maybe ten patients. Since that, the subsequent 80, we've had zero mesh extrusion.

Q. That you're aware of; correct?

A. That I'm aware of, yes.

And I also forgot, so just in case you look it up, the SUFU, we are presenting 100 urethrolyses for obstruction

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following slings. That's at the AUA. I'm sorry.
Q. What's a urethrolysis?
A. Oh. Cutting of sling. They're obstructed. And that's, again, at the AUA, not the SUFU. I'm sorry.
Q. What types of slings are these?
A. The majority are autologous, 53; 30, roughly, are synthetics, suprapubic or TVT®; they had a few transobturators and then some Burch and MKs. That was the minority.
Q. Where did these cases come from? Were they original surgeries done at Mayo or somewhere else?
A. No. They were all referred in.
Q. So the majority of these urethrolyses involved autologous slings?
A. Correct.
Q. What was the N on the obese cohort?
A. 90. Oh, on the obese, the subset? I don't recall.
MR. SNELL: Take another little break, if you don't mind.

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(Recess, 4:13-4:32 p.m.)
MR. SNELL: Could we mark this.
(Exhibit Elliott-8 was marked for identification.)
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit Number 8. You see it's a document that states that you have been paid one thousand, six hundred -- back up.
Doctor, I've handed you Exhibit Number 8.
Do you have it in front of you?
A. Yes, I do.
Q. And that document states that you have been paid $167,727 to date; correct?
A. That's what it states, yes.
Q. And that document is dated October 17th, 2012; correct?
A. Correct.
Q. And is it correct that as of October 17th, 2012, you have been paid $167,727?
A. Well, as I stated before, I don't know how much I've been paid, but that's how much it states here. I have no reason to

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suspect it's wrong.
Q. Now, your rate is $700 an hour even though that document states it is 750; correct?
A. Yes. It is 700 but, you know, it does say 750. But yes, I am getting paid 700 per hour.
Q. When did you arrive in New Jersey to give your deposition?
A. Monday night, whatever that was. Touched down at 11:00 at night.
Q. How many hours have you spent preparing for this deposition between the time when you got on the plane to come to New Jersey up until this morning before you sat down?
A. Okay. Travel time was six, seven hours. I don't know what it was. But there was no prep time in it. That was just travel.
And then in the morning of Tuesday there was an hour and a half, two hours in the morning. There was roughly eight or nine, maybe up to ten hours with Mr. Anderson on Tuesday. And then in the

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evening I put in another hour to two hours. And the same would be said then for Wednesday. Essentially, the -- roughly, the same amount.
Q. Roughly somewhere between 10 and 14 hours on Tuesday and Wednesday --
A. Correct.
Q. -- altogether.
A. Correct. That is correct. Each day.
Q. Per day.
A. Per day. And then this morning, roughly an hour and a half.
Q. So somewhere between 22 and 28 hours, altogether.
A. Yeah. I'd have to add it up, but that sounds about right, yeah.
Q. And you haven't billed for that, obviously.
A. No, I have not. Yes.
Q. When was the last time you issued a bill?
A. October 31st.
Q. Do you bill at the end of every month?

A. Yes. If I've done work, I bill, obviously.
Q. Besides the 22 to 28 hours that you've spent -- strike that.
Do you know if this $167,727 includes your bill from October 2011?
A. I would assume it did not because I submitted it to them on October 31st.
Q. Can you give me your best approximation how many hours you billed for in October?
A. I don't know the number of hours on that.
Q. Your best approximation is that --
A. I can give you a dollar amount because I know that because I just deposited the check.
Q. Okay.
A. It was roughly 25,000.
Q. And for the month of November, other than the 22 to 28 hours you spent preparing in the past couple of days, have you spent any other time on this matter?
A. Yeah. I continued from November

1st until leaving of doing review work. I don't know what -- I -- I do have a record of it. I don't have it with me. That's at my home. And I don't know the number of hours. It would be in the range of 20 to 30, maybe. Maybe. I could be quite off, actually.
Q. So approximately 20 --
A. 20 to 30.
Q. -- to 30 hours.
A. Prior to leaving to come to New Jersey.
Q. And approximately 22 to 28 hours since you've arrived here in New Jersey.
A. Correct. Except that has not -- not counted the deposition today. So --
Q. Yeah.
A. -- each minute counts.
Q. Do you have a separate company which the checks are made payable to?
A. No.
Q. They're just made out to you personally?
A. Correct.
Q. Did you seek any approval from

the Mayo Clinic with regard to your role as an expert in the mesh litigation?
A. No. This is all private time.
Q. Do you have your report handy, the annotated one?
A. Yes, I do.
Q. Is that your version of the report?
A. No.
MR. ANDERSON: It's mine.
THE WITNESS: This is Mr. Anderson's.
BY MR. SNELL:
Q. The November 7th, 2012, supplemental report to which we have objected and I've stated our grounds for said objection --
MR. ANDERSON: Yes.
BY MR. SNELL:
Q. -- you did not in that report disclose any new general opinions; correct?
MR. ANDERSON: Objection.
THE WITNESS: No. That was pertaining specifically to Gross and Wicker.
BY MR. SNELL:

Q. Are all opinions you plan to offer, are all your general opinions that you plan to offer contained within this June 15th, 2012, report and the supplemental November 14th, 2012, report, which you state that they further supported your opinions as set forth in the original report?
MR. ANDERSON: Just objection to the question.
THE WITNESS: I cannot say. I mean, I am ongoing continuing to do research and thought with this. If something new does arrive, that could change it, but right now I have no knowledge of anything.
BY MR. SNELL:
Q. As we sit here today, all of your general opinions are contained in the general report and the November 14th, 2012, supplement; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Yes.
BY MR. SNELL:
Q. On Page 8, this contains a summary of your opinions?

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A. Yes.
Q. And that's Pages 8 to 11?
A. Yes.
Q. And do you believe that this is a fair summary of the opinions you plan to offer at trial?
A. Yes.
Q. I'm going to ask you about a couple of these.
The first one -- are you with me?
A. Yes, I am. Number one, I assume but --
Q. Yes.
A. On Page 8. Yes?
Q. Page 8. Yes. Thank you, Doctor.
This says, "patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including the Prolift System, do not have demonstrable improvement in symptomatic results over traditional, non-mesh repair"; correct?
A. Yes.
Q. You have reviewed clinical studies -- let me back up.

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Is it your opinion that any non-absorbable transvaginal synthetic mesh for the use in pelvic organ prolapse is not an appropriate option for surgeons?
A. That's not what I state.
Q. I'm asking --
A. That's just what I state right here. Not demonstrable improvements in symptomatic results over the traditional repair.
Q. My question is, is it your opinion that doctors should not use non-absorbable transvaginal synthetic mesh for pelvic organ prolapse?
A. My opinion, again, we've got it outlined very well in here, stated but, briefly, my opinion is the routine, common use of mesh for pelvic organ prolapse is not appropriate, based upon the data.
Q. Do you believe a surgeon who chooses to use transvaginal mesh to treat prolapse is violating the standard of care by using transvaginal mesh --
MR. ANDERSON: Objection.
BY MR. SNELL:

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Q. -- for prolapse?
MR. ANDERSON: Sorry.
Objection.
Go ahead.
THE WITNESS: I don't believe a standard -- a standard of care -- let me back up.
A standard of care regarding pelvic organ prolapse is still evolving. It would be incorrect for me to say that a surgeon is violating the standard of care. It is not malpractice to implant a mesh, okay, because that's not established. Is it efficacious, does it benefit the patient is a different story. That's what I'm having a very strong opinion on.
BY MR. SNELL:
Q. And is it your opinion that say Prolift® mesh does not benefit any patients whatsoever?
A. I have not stated that, no.
Q. Is it your opinion that the use of non-absorbable transvaginal synthetic mesh does not benefit any patients out there?

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A. There is -- as you stated that question, just now --
Q. Yes.
A. -- there is a, I think, a benefit in stress urinary incontinence.
Q. Do all patients who receive Prolift® have complications?
A. No.
Q. Do all patients who receive transvaginal mesh to treat prolapse have complications?
A. No.
Q. You will acknowledge that in the medical literature that patients who have received Prolift® have received efficacious treatment of their prolapse; correct?
A. I --
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I -- I do agree with that. I also agree that the majority of Pinto cars did not kill people or the majority of Firestone tires are good. So I'm not saying banning all. I'm saying that the complications. That was the issue.

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MR. SNELL: Move to strike everything after "I do agree with that."
BY MR. SNELL:
Q. You would agree that patients implanted with Prolift® have demonstrated improvement in symptomatic results, according to the medical literature?
A. Yeah.
MR. ANDERSON: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. You would agree that patients implanted with Prolift® have demonstrated improvements in quality of life, according to the medical literature.
A. Yes, some of them have. Yes.
Q. That's what I'm asking.
Some patients, not every single one; right, Doctor? Because is there a surgical procedure you can point me to to treat prolapse where every patient has efficacy and no complications?
MR. ANDERSON: Objection to the form.
Go ahead.

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THE WITNESS: No.
MR. SNELL: Okay.
BY MR. SNELL:
Q. Patients implanted with Prolift®, in general, have improvement in their PSI scores; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I can't answer that.
BY MR. SNELL:
Q. Why not?
A. Because there is an extensive amount of data out there that mesh degradation, shrinkage, contraction, et cetera, continues for years, so I cannot comment what will be happening 10, 20, 30 years on down the road.
Your comment in general implies 51 percent, and I don't know, will we cross that at some point in time.
Q. Overall, patients who have been implanted with Prolift® have had improvement in their anatomic prolapse scoring; correct?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: And your definition of overall is -- just so I'm clear, so I'm answering your question, overall means?
BY MR. SNELL:
Q. The majority.
A. The majority.
Q. You've seen in the studies that they identified POPQ scoring; correct?
A. Yes.
Q. In the prospective studies; correct?
A. Yes, I've seen it.
Q. In the retrospective cohort studies; correct?
A. Yes, I have.
Q. In the randomized, controlled trials; correct?
A. Yes, I have.
Q. And overall, patients on Prolift® have improvement in their anatomic prolapse scoring after Prolift® implantation; correct?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: I believe the anatomic repair has been vastly and incorrectly reported as being good. And then to answer your question, yes, I agree, Prolift® has anatomic improvement in the majority of patients.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. You would agree that Prolift® has anatomic improvement in the majority of patients; correct?
MR. ANDERSON: Objection. Asked and answered.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Opinion Number 5 on Page 9, Doctor.
A. Yes.
Q. You state, "There was no need for the Prolift® system...to be sold and marketed as a surgical treatment and procedure for pelvic organ prolapse as there were safe, effective and reasonable alternative surgical treatments available at

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the time," et cetera; correct?
A. Yes.
Q. If a surgeon has used Prolift® and he or she believes that it has, in general, benefitted his or her patients --
A. There was no question there, was there?
Q. No. I'm in the process of formulating it.
MR. ANDERSON: Formulating.
THE WITNESS: You looked at me. I thought --
MR. ANDERSON: Off the record.
(Discussion off the record.)
BY MR. SNELL:
Q. If a surgeon has used -- strike that.
If a surgeon used Prolift® in his or her patients and they believe that Prolift®, in general, benefitted his or her patients, would you be critical of that surgeon's decision to continue to use Prolift®?
MR. ANDERSON: Objection.
Go ahead.

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THE WITNESS: With the available data present, readily present in the literature, with no improvement in symptomatic results, regardless of what a surgeon believes, they are taking those patients and increasing their potential risk for devastating complications.
I would be very confident and have at meetings stated surgeons better be very, very careful in selecting these individuals because they are going to be damaging some people permanently.
BY MR. SNELL:
Q. I thought we earlier agreed that, in general, patients who have received Prolift®, per the medical literature, do receive symptomatic improvements.
A. I agree with that.
Q. You just made a statement that there was no improvement of symptomatic results in your previous answer.
Were you taking making some type of comparison or --
A. I see.
Q. I just don't track you.

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A. No. I misspoke.
In comparison -- what I should have stated in there is no symptomatic improvement in comparison to traditional repair.
Q. Okay.
A. So, yeah, that's a very good pickup.
Yes, Prolift® has symptomatic improvement but not more than traditional repair.
Q. You've read the Altman New England Journal 2011 article involving Prolift® versus anterior colporrhaphy?
A. Many times, yes.
Q. The primary point there was a composite primary end point of POPQ staging --
A. That was --
Q. -- and subjective reporting of bulge; correct?
A. That is -- I'd have to look at it but, as I recall, yes, that's correct.
Q. And in the Altman study Prolift® was statistically significantly better than

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colporrhaphy in that primary composite end point; correct?
A. Now, is this the manuscript where he states in there there was no Ethicon involvement to The New England Journal of Medicine editors and Ethicon employees knowingly changed the document or suggested to him to change the document, which to me is medical fraud?
Q. It's The New England Journal article by Altman. You and I know exactly which one it is.
MR. ANDERSON: Objection to that characterization.
BY MR. SNELL:
Q. I'm the one asking the questions, Doctor, not you, so just answer my questions, if you can.
A. That article --
Q. Let me back up and ask my question because I actually didn't get an answer.
A. That's fine. Sure.
Q. In the Altman 2011 study Prolift® was statistically significantly better than

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colporrhaphy in the primary end point; correct?
A. I will politely, not to be difficult, refuse to answer that question because this is medical/scientific fraud.
Altman lied on that declaration to The New England Journal of Medicine. I cannot trust any of that data on there. This is based upon my experience as being an editor and reviewer in eight different medical journals.
If anybody were to know that there was a lie like that, that data is excluded, he would never be allowed to publish in the United States. So I cannot trust that data at all, no matter what was said.
MR. SNELL: Objection. Move to strike.
BY MR. SNELL:
Q. Are you aware of any changes with the underlying data, with the whole, entire transvaginal Nordic group during the collection of that study?
MR. ANDERSON: Objection.

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THE WITNESS: How can -- how can I trust it? I mean, I --
BY MR. SNELL:
Q. I'm asking you, are you aware?
A. I am aware --
MR. ANDERSON: Same objection.
THE WITNESS: I am aware in the deposition of Hinoul --
MR. ANDERSON: Hinoul?
THE WITNESS: -- Hinoul where he describes changes that were made in the manuscript.
I cannot trust the data and nor can any urologist or gynecologist.
MR. SNELL: Objection. Move to strike.
BY MR. SNELL:
Q. So you can't answer any questions about the Altman study because of this issue you've identified.
A. Anything I state about the data in there, I can't believe that necessarily that data is true.
Q. So you don't believe the rate of erosion in that study?

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A. I don't know.
Q. You don't --
A. Everything is suspect.
Q. You don't --
A. That paper will get rejected from The New England Journal of Medicine if the editors find out about it.
MR. SNELL: Objection. Move to strike.
BY MR. SNELL:
Q. You're not -- you don't believe the rates of complications reported in the Altman study?
A. How could I --
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: How can I trust it? Every --
BY MR. SNELL:
Q. I'm asking you, I'm just saying, it's a yes or no answer. Either you don't or you do.
MR. ANDERSON: Objection.
THE WITNESS: I do not trust

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the data.
BY MR. SNELL:
Q. And, therefore, you're not prepared to answer questions about it, other than this same spiel that you've given so far?
MR. ANDERSON: Objection to the characterization of his testimony.
THE WITNESS: Yeah. Actually, I'm going to be quite offended at calling it a spiel.
The honesty -- everything that we rely upon as editors of journals and in scientific publication is trusting that what we are presented is accurate and truthful, to the best of the author's capabilities.
When I read in New England Journal of Medicine that he states no Ethicon involvement, no employees' involvement -- I'd have to get the actual document and see exactly what the words were saying -- then I read internal documentation and Hinoul's, whatever his name is, how you pronounce it, where he says there was multiple changes made, which Dr. Anne Weber

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in her supplemental report details extensively the changes, subsequently, everything is suspect. The complications that -- he reports 16.9 percent erosion. How do I know it's not 24? How do I know it's not 5? I can't trust it.

MR. SNELL: Okay. Move to strike.

MR. ANDERSON: That was your question.

THE WITNESS: It is an issue of integrity.

BY MR. SNELL:

Q. When you said there was no improvement in symptomatic results in comparison to traditional repairs, are you basing that on -- on Page 14, the up-to-date prolapse definitions as articulated by Dr. Weber?

A. That was pertaining to anatomic results. I have a detailed explanation in my expert report, Page -- beginning on Page 38 where I talk about symptomatic results, which spells it out in detail.

Q. And just so I'm clear, too, when

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you talk about in comparison to traditional repairs, what repairs are you referring to?

A. Well, that's going to be specific if we're talking about anterior Prolift® and we're comparing it to anterior colporrhaphy.

Q. Okay.

A. If we're talking about posterior colporrhaphy, then we're talking about posterior Prolift®, and then total Prolift® is then the various different procedures, which there are going to be several in there.

Q. Can you give me those?

A. Well, there would be sacrospinous fixation, sacrocolpopexies, and then again we're probably talking about the McCall's culdoplasty, the Mayo culdoplasty. There's other ones in there. Those are going to be the major percentage-wise.

Q. Is it correct that in patients who have prolapse in more than just the vaginal vault, if a doctor chooses to do a sacrocolpopexy in the majority of cases, they will also do a concomitant adjunct procedure like a colporrhaphy or something

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else?

A. Well, your question is more than the vaginal vault. The vaginal vault is everything. So, I mean, are you referring to something else?

The vaginal vault is implying, I mean, everything is coming on out, the entire eversion of the vagina, so, by definition, that's anterior, posterior and apical. So are you referring to something else, suggesting that I'm missing?

Q. Yeah.

A. I think I'm missing the question, then.

Q. Yeah, I think we're not communicating.

Well, let me ask it this way: Are concomitant prolapse surgeries commonly done alongside a sacrocolpopexy?

A. Okay. Now I understand your question.

That depends on what you're doing at the time of sacrocolpopexy.

Q. Okay.

A. The way I do it and those

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pictures that you saw were using, having those anterior and posterior arms, which are quite long. That way, you can elevate the entire vaginal vault with that, anterior, posterior, and apical.

There have been descriptions of just putting a cap at the apex of the vagina. If you do that, you will not be supporting anterior or posterior, at least very well.

Q. Okay.

A. And so then that answers your question, would they do a concurrent anterior/posterior colporrhaphy. I do not in my practice.

Q. Are you familiar with the randomized, controlled trial by Withagen --

A. Yes.

Q. -- involving Prolift®?

A. Yes.

Q. And what did that study show with regard to primary end point?

A. I'd have to get the paper out and review it.

Q. Did you discuss the Withagen

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paper in your report?
A. Yes, I did.
Q. Can you just point to me where?
A. Well, it will be in here -- Page 38 under the subsection "Anatomic Results," the very top line, first paragraph, Reference Number 40 discusses her paper. And it's referencing anatomic superiority over traditional repair, which there was none in the paper.
Q. I'm sorry. Say that again?
A. Specifically, and then reading directly out of my document, Page 30, transvaginal mesh posterior and transvaginal mesh apical POP repairs did not produce any -- it says, provide any anatomic superior results benefit compared to traditional transvaginal non-mesh POP procedures, Reference 40, which that is one of them, Withagen. There's three others in there that I reference.
Q. The Inglesia study you referenced in your --
A. Yes.
Q. -- report.

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Do you know if that study was adequately powered?
A. I'd have to look at it to determine that.
Q. Do you know what the rate of mesh exposure was with the Prolift® arm?
A. I -- I would have to look again at it. Off the top of my head, it was like 15, 17 percent, something like that, and then the study was terminated prior to significant enrollment.
Q. Do you recall what the rate of suture erosion was in the other arm?
A. No, I do not. I'd have to look at the manuscript.
Q. Do you know if the authors reported a statistically significant difference in the rate of mesh exposure versus suture erosion in the two arms?
A. Again, I'd have to look at the manuscript to determine that.
Q. Page 9.
A. Okay.
Q. Back to Paragraph 5, we were talking about.

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A. Okay.
Q. You mentioned there's the risk of serious injury.
A. Yes.
Q. Do you see that in Paragraph 5?
A. Yes, I do.
Q. Would you agree that there's a potential risk of serious injury with the sacrocolpopexy?
A. Yes.
Q. Would you agree there's a potential risk of serious injury with the sacrospinous ligament fixation?
A. In a magnitude and frequency and intensity and delayed onset difference but, yes, there is risk there.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. Would you agree that there's a potential risk of serious injury with the sacrospinous ligament fixation?
MR. ANDERSON: Objection. Asked and answered.
THE WITNESS: There is -- there is risk there for serious injury, yes.

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BY MR. SNELL:
Q. Would you agree that there's a risk of serious injury with colporrhaphy?
A. Yes.
Q. In the next paragraph, B-1 --
A. Number 1? Yes.
Q. Yes. On Page 9 of your report.
A. Yes, I'm looking at it.
Q. You say, Synthetic transvaginal meshes for POP, including... Prolift®...subject patients to needless danger through increased risks not present in traditional, non-mesh surgery."
Do you see that?
A. Yes, I do.
Q. Is that the same data set we're talking about? Strike that.
Is that the same surgery set we were referring to before, anterior/posterior colporrhaphy, sacrospinous ligament, sacrocolpopexy, McCall's culdoplasty, Mayo culdoplasty?
A. Yes. Any time I use the words "traditional, non-mesh," unless we're talking about a specific compartment, it

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would be all inclusive.
Q. And what increased risks do you believe are attendant with the Prolift® system as compared to traditional, non-mesh surgery?
A. Again, I outlined that in the expert report very thoroughly, which we can go through that complications section.
Q. Okay.
A. Go through each one. It -- it's on Page 5 of the Table of Contents. I go through the safety, which then starts on Page 42 or so. Actually, on Page 41 is the introduction and then we have it all -- all the subsets of impaired vaginal healing, contiguous organ injury, voiding dysfunction, contraction.
Q. I'm sorry. Where are you at, Doctor?
A. Oh, I'm sorry. I'm just reading off of the Table of Contents beginning in -- the text itself begins on Page 41 and then I'm just reading the points because you asked what was increased and so that's what I was going through.

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Q. Okay.
A. And then I -- foreign body reaction, increased foreign body reaction, degradation, pain syndrome, sexual function, dysfunction.
Q. And is it your opinion that these potential risks are increased with Prolift® compared to the traditional surgical repairs?
A. Yes.
Q. Are they statistically significantly increased?
A. I can't speak to statistically significant. We'd have to go to study by study.
Q. Have you done that? Have you done that?
A. I have looked at the frequency of it looking at the TVM studies, the Hinoul study, the various different French group studies and looked at them.
Q. Have you compared them statistically, though, to see if there's any statistically significant difference?
A. Well, there's the randomized,

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controlled studies by Withagen, who compares the erosion rates versus the non-mesh groups showing what, 16.9 percent erosion, something like that, I might not be exact, which is statistically significant over the other groups.
And then we also have to compare in there, you can't compare apples to apples because you have like, again, the severity of the problem. Suture erosion versus mesh erosion are two completely separate problems.
Q. In the cohort of mesh exposures in Withagen do you happen to remember how many of those were conservatively treated with just either watchful waiting or estrogen cream?
A. I would have to look at the study to get the specific number. By and large, it's roughly 50 percent could be treated conservatively, 50 percent require surgical re-operation.
Q. So it's your opinion that 50 percent of women who have mesh exposures can be treated conservatively?

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A. Well, that's a rough, across-the-board statement. It's pretty much -- in many of the literature, it's roughly that number.
Q. With regard to Prolift®, is it your opinion that approximately 50 percent of mesh exposures can be treated conservatively?
A. Correct. And the other 50 percent require surgical exploration.
Q. And the conservative ways of treating a mesh exposure with Prolift® would include just watching it and doing nothing; correct?
A. Yes.
Q. You can use the topical application of estrogen; correct?
A. Yes. As long as there's not a contraindication.
Q. Any other conservative way of treating mesh exposure with Prolift®?
A. I believe those are the two big ones.
Q. And of the 50 percent of patients who you believe with Prolift® have to have

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some type of surgical intervention for their mesh exposure, a majority of them are able to have the mesh excised and treated on one occasion, according to the literature; correct?

A. I'd have to look at the literature. I don't know off the top of my head the percentage that one treatment. Probably many can, but I don't know of the exact number.

Q. Have you seen any studies on Prolift® that demonstrate that a high number of the patients with mesh exposure who need an intervention have to undergo multiple mesh revisions?

A. I've seen a significant number and taken care of them myself in my own practice where one treatment does not do it and they require multiple treatments.

Q. In the literature is there a number that you are aware of that you think accurately describes the number of Prolift® mesh exposure patients who need more than one surgical procedure to excise that mesh exposure?

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A. I don't believe there's an accurate number out there because we don't know the denominator in the situation.

Q. In some patients who need excision for a mesh exposure is it correct that the surgeon can in 10 or 15 minutes perform an excision and resuture of that mesh exposure?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: It depends upon the magnitude of the erosion. So to answer your question, if it were a very small erosion, that possibly could be done. If it's a large erosion, it can't be done.

BY MR. SNELL:

Q. If it's a mesh exposure of two to three millimeters, would you agree that in those types of mesh exposures a surgeon can go in, excise that exposure and re-suture it within 10 to 15 minutes?

A. Too many variables in that: The patient, her degree of pain, if there's a concurrent infection. If any of those are present, you would not be able to do that.

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If all of those are excluded, then you might be able to. So I can't give you a definitive answer because, again, there's too many variables.

Q. How many Prolift® mesh exposures have you treated?

A. I wouldn't be able to break it down because I have not looked at specifically Prolift®.

In my practice, the majority are Apogee®, Perigee®, Elevate®. I think that's just because of the regional differences of where they're implanted. I know I've taken care of at least -- well, let me back up. Well, I cannot recall a Prolift® exposure.

Q. So as you sit here today in your deposition, you cannot recall ever treating a Prolift® mesh exposure; correct?

A. I cannot recall. It doesn't mean it didn't happen, but I cannot recall it.

Q. But the answer to my question is correct.

MR. ANDERSON: Well --

BY MR. SNELL:

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Q. Correct, you do not recall it.

A. I do not recall it, yes.

Q. The majority of mesh exposures that you have treated for prolapse surgeries involved Apogee®, Perigee® and the Elevate® products; correct?

A. That is correct.

Q. How many, in combination, Apogee®, Perigee® and Elevate® mesh exposures have you treated?

A. I'm going to give you a rough number: 15 to 20.

MR. ANDERSON: Can I just get a clarification?

By exposures are we including erosions, extrusions?

MR. SNELL: That's a good --

MR. ANDERSON: Because sometimes you're saying "exposure" and he's answering with "erosion." I just want to make sure that the record is clear on what we're all talking about.

Is that fair?

THE WITNESS: Absolutely. Yeah.

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BY MR. SNELL:
Q. So, Doctor, when I'm talking about mesh exposures, are we communicating, were you talking about the same thing --
A. Yeah.
Q. -- or are you talking about something totally different?
A. For the record, let's put it down, when I hear "erosion," that means perforation into an organ. Bladder is what I usually see, that's what usually gets sent to me, and urethra. Exposure and extrusion are essentially going to be synonyms to me.
Q. Yeah. What I was talking about is mesh exposure, and I think you and I were on the same page.
A. I believe so, yes. And that would -- the answer would be roughly 20 vaginal exposures.
Q. And then the same holds true, as you sit here today, you cannot recall ever treating a Prolift® mesh exposure; correct?
A. I cannot, no.
Q. Now mesh erosion. Have you ever treated a Prolift® mesh erosion, as you have

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defined how you consider erosion?
A. I've had to deal with roughly 15 or 20 mesh erosions, which that's what's more commonly sent to me as opposed to the gynecologists at our institution. Which ones were Prolift® versus the other ones, I just can't recall because I didn't keep track of that.
Q. Would it be accurate that the majority of mesh erosions that you have treated have been Apogee®, Perigee® or Elevate®?
A. I can't say that because, again, I don't -- I don't know --
Q. Okay.
A. -- which ones.
Q. In the 15 to 20 cases of mesh erosion that you have treated, were the majority of them where the mesh eroded into the bladder?
A. Bladder, correct. And then one -- two that I can think of were urethral.
Q. Now, when we're talking 15 to 20 mesh erosions, are you talking just prolapse or are you including urinary incontinence

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meshes in there too?
A. I'm including both.
Q. Of the 15 to 20 mesh erosions, do you know how many were for urinary incontinence meshes versus prolapse mesh?
A. The majority probably would be for incontinence.
Q. How many prolapse mesh erosions have you treated?
A. We're talking ten or so.
Q. Now I'm confused. You said you've treated 15 to 20 mesh erosions, which included prolapse and urinary incontinence; correct?
A. Yes.
Q. And you also testified the majority of those were urinary incontinence; correct?
A. Okay. Yes. Yes.
Q. So --
A. Well, it gets confusing because I don't keep a record.
I can tell you I have had nine where we've done laser resections of, using Holmium laser when they're in the bladder or

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in the urethra. I would have to review the database as far as what was causing what, but I don't have those records. So that's why a lot of this is I'm, you know, guesstimating over five, six, seven years.
Q. Uh-huh.
A. So that's why there's going to be a little bit of difficulty.
Q. Well, is it your best estimate that you've treated less than ten mesh erosions specific for prolapse mesh?
A. I would say it's accurate.
Q. And you've treated less than ten mesh erosions specific to prolapse mesh over the last five to six years; correct?
A. In the guess, yes.
Q. And for the prolapse mesh erosions, how did you go about treating those, the revisions?
A. If there is an isolated piece within the bladder and where it is very easy to get to, we will attempt to do, use a laser on it to resect it to avoid the morbidity of an open surgery. If it is a large area of erosion, then we'd have to do

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that open.
Q. So in your practice you attempt to treat both mesh exposure and mesh erosion in the most conservative manner first.
A. Absolutely.
Q. Are you of the opinion that every case of mesh exposure, regardless how -- strike that.
There are some cases of mesh exposure that are actually asymptomatic; correct?
A. Well, I assume so. If they're asymptomatic, we might not be seeing the patient, so I don't know. Yes.
Q. You've seen it described in the literature in clinical studies involving Prolift® and other prolapse meshes that there are mesh exposures which are asymptomatic and, as described, that means the patient doesn't complain of it, it is detected upon vaginal examination; correct?
A. Yes.
Q. And are you of the opinion that regardless of how small the mesh exposure is, a surgeon should seek to go in and take

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out all the mesh?
A. Take out, explant the entire mesh?
Q. Yes.
A. I would not be of that opinion. That is a very, very difficult surgery, very morbid surgery. So no. My opinion -- and this may vary from others -- you have to do the -- attempt the most conservative first.
Q. That makes sense; right?
Doctor, if you can treat it with estrogen cream, why not treat it that way as opposed to doing surgery on it; correct?
A. Yes. The individuals I'm seeing have already been treated with estrogen and it's failed, so very rarely am I seeing those individuals.
Q. But for an individual who presents with a mesh exposure and it's the first-time presentation, you would agree that conservative treatment is the best option.
A. Not necessarily. It depends upon the size of the erosion.

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Q. I didn't say erosion. Did I say erosion? I thought I said exposure.
A. Okay. Yeah. That's -- yes. I heard "exposure," I said "erosion."
Q. Let's just back up.
For an individual who presents with a mesh exposure for the first time you would agree conservative treatment is the best option; correct?
A. And then what I'd say is it depends upon the size of the exposure, if there is pelvic infection going on or not.
So large exposures, painful patient, obvious induration of the tissues, then estrogen may not be advisable. Small exposures, otherwise healthy, minimally symptomatic, then yes, estrogen replacement.
Q. If it's a smaller -- let's take large exposures out of the picture.
How do you -- well, how do you define large exposures? Do you have a benchmark? More than 10 millimeters, 20 millimeters?
A. No. I would say in my practice, if we're talking greater than one centimeter

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square, we are now into the larger realm. And then certainly two centimeters square.
Q. So this, what I've drawn, is this something you would consider a large exposure?
A. I would consider that larger because that's not the entire area of the problem because underneath that bacteria has gotten into the mesh.
So if you start exposing that, you're going to have denuded, devascularized vaginal mucosa. So a one-centimeter exposure, one-centimeter-square exposure, visually corresponds to possibly two or three centimeters of underlying degraded tissue and mesh. So that's what I'm saying is you can't -- that's the tip of the iceberg is the best analogy.
Q. Well, is that the case in all cases -- in all cases of one-centimeter exposures, is it your opinion that two to three centimeters of tissue below that are compromised?
A. No.
Q. Are you aware that one-centimeter

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exposures have been able to have been treated conservatively without surgery?
A. I'm also aware of --
Q. That's a yes or no answer. Give me the answer and then we can talk about what you're also aware of.
Is that correct?
A. Yes. Yes.
Q. All right. What were you about to say you're also aware of?
A. Okay. What -- you have to look at each individual differently. Again, the pain tolerance, the anxiety level of the patient, those factors, also, the vaginal exam.
You are absolutely correct, an isolated, small, one centimeter, where the tissue is growing through the mesh and you can just barely feel it is one thing versus another one where you can look at it, there's a foul smell, the patient is very uncomfortable when you touch it, and you get the impression this is a bigger situation. So you cannot go off of just a one-centimeter-square rule.

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Q. Okay.
A. I'm saying we have to think about all of the options when we see somebody.
Q. What percent of your mesh exposure cases had concomitant infection?
A. We never cultured them so I cannot say on that. When you look at the mesh and there's granulation tissue and the mesh is exposed, that is a colonized mesh. That, by very strict definition, is an infected mesh. The severity of the infection may be mild.
Q. So you never cultured any of these mesh exposures for different types of organisms --
A. No.
Q. -- to see the count of pathogenic versus non-pathogenic bacteria?
A. It will be all contaminated. If we put a probe into the vagina, it's going to be contaminated because we don't know what to do with those kinds of results.
I have done it where there's tracking. Just last week, there was tracking going up the -- toward the

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obturator foramen, where you could actually put your finger in a full digit's worth. That I cultured. I don't know what the results are on it because I'm not back home.
So, again, there can be no absolutes. Case-by-case situation.
Q. Well, in those cases of mesh exposure you treated, how many of them had concomitant elevations of white blood counts?
A. We don't routinely check a CBC unless they're going to the operating room.
Q. Well, I thought you said that by the time, when they got to you, the majority of them, you were doing some type of mesh excision.
A. Yes. And then the CBC, specifically the white count, is not necessarily part of the routine evaluation. White count is only going to be elevated if we're talking about a systemic type of infection. These individuals that I have dealt with have not had systemic infections.
Q. So on the mesh exposure cases you've treated they have not had systemic

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infections; correct?
A. No. They've been afebrile.
Q. And they haven't had elevated fevers; correct?
A. That's what afebrile is. Yeah. No. No, they have not had an elevated temperature.
Q. Now, for the mesh erosion cases, you've said if there was an isolated piece of mesh in the bladder, you would use a laser to resect the mesh?
A. That would be one of the options. They'd have to be -- so we would attempt to do that if the mesh were in an ideal location, we could get to it, and it appeared that we could easily resect it.
And that is an evolving study. At this point, we have nine patients that we've done that in, and we are going to be attempting to publish that data or present that data to AUA in 2013.
Q. That is a more conservative way of treating the mesh erosion, in your opinion; correct?
A. Correct. Yes.

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Q. Than the open surgery; correct?
A. That's correct. I have done the open surgery. It is very difficult. And I'm not necessarily convinced that we can adequately solve the problem with that. So I try -- my goal is to try as conservative as possible.
Q. What type of open surgery are we talking about?
A. Transabdominal.
Q. So you make a transabdominal incision so you can get to and visualize the bladder --
A. Yeah.
Q. -- see if there's a mesh exposure, mesh erosion to the bladder?
A. Yeah. Mesh exposure to the bladder or if there's banding also. But yes, because we can't -- to do it transvaginally you -- the tissues are densely adherent to this mesh. Transvaginally, I don't know a way of being able to do that without creating a bigger hole and creating a vesicovaginal fistula, so that's why we attempt it

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transabdominally.
Q. Are you aware of surgeons who -- strike that.
Are you aware of surgeons who treat mesh erosions transvaginally?
A. I am not aware of that. The treatment as far as dealing with this -- just like the nomenclature of the problem is evolving, I am by no means stating that the way I do it is the absolute correct way. We are all figuring this thing out, and that's why the attendance at meetings in national, international are key to talk about this.
Q. So is it correct that as you sit here today, you do not know how to treat a mesh erosion transvaginally?
A. No. I know how to -- I could do it. I'm -- I can take care of vesicovaginal fistulas transvaginally. I'm prepared to do that.
I don't know of the ones that I have seen that I would be able to get the mesh out and get the bladder healthy, trim off the ischemic or infected sections, close that without injury to the ureteral orifices

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and then subsequently close the bladder -- close the vagina and hope it's going to work. If somebody can do it, great. I'd like to see that study and video and follow-up.
Q. In the mesh erosion cases that you've had -- strike that.
In the mesh erosion cases you have had involving prolapse mesh for which you --
A. Prolapse. Okay. Yes. I'm sorry.
Q. SUI on the side.
A. Yeah.
Q. For the mesh erosion cases you have dealt with involving prolapse mesh for which we agreed that it's likely less than ten -- correct?
A. That is correct.
Q. How many of those patients had systemic infections?
A. None of them had clinical evidence of fever to suspect that. They had localized discomfort and discharge.
Q. And if there was a -- if there

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was a mesh erosion for prolapse surgery that you treated -- strike that.
For one of these mesh erosion surgeries that you've performed regarding prolapse did you attempt to remove all the mesh in every case or did you start more conservatively and kind of handle things as they came?
A. I -- first of all, I think it is next to impossible to remove all of the mesh, with the arms, to -- to burrow it out of the muscles. Physically, that is very, very difficult.
In comparison, a recent case of a TVT® erosion, it was horribly difficult, where we used big scissors to chomp the thing out. And those are easy, compared to pelvic organ prolapse meshes. So no, my goal is not to go and get rid of all the mesh. My goal is to go in there and to remove what problem can be easily done.
And the reason is not because I'm afraid of the work, it's that I'm concerned that I might not solve the problem, I might create more issues in

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trying to deal with it. And that's my personal technique. Others at my institution have a different approach.
Q. Mesh erosions from prolapse can come in different sizes; correct?
A. Yes.
Q. Different degrees of severity; correct?
A. Yes.
Q. And if you had a small mesh erosion from a prolapse mesh, you wouldn't need to remove all the mesh that had been put in in the first place; correct?
A. Again, you have to look at the totality of the patient, what all they're describing.
My philosophy, which is specifically me, is try and do as little as possible because the mesh in the belly is a viper. You start opening it up, you expose more of it, spill urine on it, and you might be creating more of an inflammatory response.
So to answer your question, if there's a small mesh erosion, my goal is to

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do as little as possible. But I have been burned doing that, also.
Q. So if there's a small mesh erosion, your goal is to do as little as possible for treating that mesh erosion for prolapse; correct?
A. Again, looking at the patient in the totality, what all is she describing? If she's only describing voiding issues, dysuria, those types of things, then, yes, as little as possible. If she is describing intense pelvic pain and on pelvic exam I can feel banding or folding, then I will do more, maybe. It's patient by patient.
Q. It depends upon how the patient presents and her symptomatology; correct?
A. That is -- that is a fair statement, yes.
Q. And so for mesh erosion cases involving prolapse you're not of the opinion that the mesh needs to be taken out in every case; correct?
A. That is my personal opinion. And, again, this is evolving. I don't know if the -- the right answer is known yet.

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But that is my personal opinion, yes.
Q. What type of laser are you using for these resections on the more conservative way of treating mesh erosion?
A. Holmium. Holmium, H-O-L-I-U-M.
Q. Is that the brand name or is that the actual type of beam?
A. No. That's the actual beam. I don't know what company makes it.
Q. How many cases of mesh contraction --
A. Too --
Q. -- have you treated?
A. Too numerous to count. I don't know. I don't keep track. I mean, but contraction and pain and banding all in the same category, and I will not even be able to give you an estimate.
Well, I can tell you an example. The Friday before I talked to Adam Slater, November 2nd, I believe, I saw five. And the numbers are increasing from...
Q. How many cases of mesh contraction have you seen for prolapse mesh?
A. That's what I'm talking about. I

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mean, they're too numerous to count. I don't know.
Q. When was the first case of mesh contraction that you treated from a prolapse mesh?
A. Good question. I don't know. It slowly started, like a snowball or whatever that rolling down the hill, whatever that thing is called. I have no idea to give you a fair estimate or when that began. Because it wasn't really registering. It was an isolated problem that became more and more frequent.
Q. As you sit here today, you're not able to tell me when you first began -- when you first treated a mesh contraction case for Prolift®.
A. No, I --
MR. ANDERSON: Objection.
MR. SNELL: Strike that. That was a bad question. I got my words mixed up.
BY MR. SNELL:
Q. As you sit here today, is it correct that you cannot tell me when you

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first treated a case of mesh contraction from prolapse mesh?
A. I --
MR. ANDERSON: Asked and answered.
Go ahead.
THE WITNESS: I can tell you the first that I remember, which is not the first case. The first case that I remember.
MR. SNELL: Okay.
THE WITNESS: 2009. It was a patient from Minneapolis who came down to me who had a Prolift® by Dr. Kirkemo.
MR. SNELL: Okay.
THE WITNESS: And I can remember it very clearly because I asked, who did your surgery and she said Dr. Kirkemo, who I knew of his name. And she says he had died.
And so I hadn't heard that so that's why I remembered it. And that was for pelvic pain. On exam, there was contraction and banding. And I didn't think anything more of it beyond that until I got involved in this and I realized that

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Dr. Kirkemo was still alive.
BY MR. SNELL:
Q. So you're talking about Dr. Aaron Kirkemo?
A. Correct. Yes.
Q. Do you know Dr. Aaron Kirkemo?
A. I have only encountered him briefly at the Minnesota Urological Association meeting. I'd have to look -- I don't know if it's in my CV or not -- we gave a talk or sacrocolpopexy, my resident did, Dr. Igor Frank, not that that's -- that's not pertinent.
And we made the comment that the robotic -- the sacrocolpopexy itself puts the vagina in a more normal access, which is pretty much an undisputed comment or conclusion.
And he says, "I disagree. I think sacrospinous fixation is more normal."
And I said, "No, there's no data to support that. It puts it off to the right angle." And that was it.
And so that was in 2003, 2004, around that time. So that's -- that's my

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only interaction that I know of as encountering him, until that one patient. And that was not directly with him.
Q. And so you were talking about sacrospinous ligament fixation that's performed where the vagina is moved over to anchor it towards one side of the sacrospinous ligament.
A. Correct. Usually the right side, just because the surgeons are, the majority, right-handed.
Q. As opposed to the other technique where it is actually attached to both sacrospinous ligaments.
A. Correct. Yes. Which is done sometimes. But this one happened to be because he was talking off of the right side.
Q. Were you trained on -- what's that approach for the sacrospinous ligament where it's attached to both sides?
A. Yeah, I know what you're referring to, and no, I was not.
Q. That's the only time you've ever spoken to or seen Dr. Kirkemo?

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A. Yeah. And I wouldn't say I was necessarily speaking to him. I was speaking to the audience, addressing his comment, which I didn't think was accurate, based upon the medical literature.
Q. Was he talking about the unilateral sacrospinous ligament fixation --
A. Yeah.
Q. -- or the bilateral attachment?
A. Unilateral. I believe unilateral. I can't recall it specifically.
Q. What about Dr. Dennis Miller; do you know him?
A. No, I do not.
Q. Dr. Piet Hinoul, do you know him?
A. No. Never met him, either of those.
Q. Dr. Charlotte Owens, do you know --
A. No, never met her.
Q. Do you know anyone from Ethicon, besides this interaction you had with Dr. Kirkemo, who subsequently was there?
A. Yeah. To the best of my knowledge, only Dr. Kirkemo, which, again,

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is brief. Dr. Robinson I believe was in Kansas City or something like that, so I've given talks in Kansas, I believe. I don't recall exactly. So, I mean, I could have -- I don't know him.

Q. You don't have any specific recollection of knowing him, of talking with --

A. None. Absolutely not.

Q. -- Dave Robinson or --

A. Absolutely none.

Q. Other than the one case of Prolift® mesh contraction, are you aware of any other mesh contraction cases you've dealt with that concerned Prolift®?

A. Yeah. One recently where there was banding deep into the vagina. You could feel a -- a 52-or-so-year-old woman, it was actually done in the same group, Dr. Kirkemo's old group, which I get a fair bit of business from, and a very specific band and severe dyspareunia.

Q. Was that a more recent case?

A. Yes. In the past -- actually -- actually, it's been probably about three

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months, because I saw her back, and what we -- we initially had success and then the pain came, returned.

Q. The first case that you talked about of mesh contraction, were you successful in treating that?

A. No.

Q. What was the course of that?

A. Well, if you're referring to that Prolift® Kirkemo patient --

Q. Yes.

A. -- no, I was not. It was diffuse pelvic pain.

The majority of what I see, like those five patients just recently, is this diffuse pelvic pain, which I don't have any treatment for.

Q. Do you refer them to anyone who has treatment modalities?

A. Yes. Either our -- our pain clinic, sometimes our physical medicine and rehab, which deals with pelvic floor myalgia, or Dr. Antolak is close, and I will send it to him.

Q. What's Dr. Antolak's first name?

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A. Stanley.

Q. What type of doctor is he?

A. He -- well, he's a urologist and he was at Mayo and specializes in pelvic pain, and then he retired and then restarted practice up in the Minneapolis area. So if you -- if you -- just so we're clear, I do know him quite well. He is -- has given a deposition in I believe Gross's or Wicker's.

Q. Okay.

A. So I do know -- I have not personally spoken with him in four or five years but I do know him quite well from my work at Mayo.

Q. And you say he used to be at Mayo but now he's where?

A. Minneapolis area. And he runs the -- I think it's called the Midwest Pelvic Pain Clinic or something like that. It's -- it's some variant of that. And so if the patient is from the Minneapolis area and there's nothing I can do, frequently, I'll send it to him.

Q. Mayo Pelvic Pain Clinic actually collects data on how successful they are in

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treating pain syndromes; correct?

A. Well, they don't have a pelvic pain clinic, that I'm aware of. They have a pain clinic.

Q. I thought that's what I said.

A. You said --

Q. Oh, you're right. You're right. You're right. Let me rephrase it because I didn't mean to say that.

The Mayo Pain Clinic actually collects data on how successful they are in the outcomes of things such as lessening patients' pain; correct?

A. I -- I -- not to be difficult, I have no idea if they do or not.

Q. Would it surprise you that over 75 percent of the patients treated at the Mayo Pain clinic report improvements in their pain symptomatology?

A. Yeah. Improvement doesn't mean a whole lot to me because improvement could be pain going from a seven to a six, statistically improved, significant but clinically not significant.

Q. So as you sit here today, do you

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know whether Mayo Clinic's Pain Clinic offers treatment for patients which is statistically significant but not clinically significant?

A. No, that's not what I said. I'm just saying improvement in pain is good, but is it good enough? And I don't know. I have not seen or talked to anybody in the clinic of what their results are.

Q. You haven't looked at their Website to see what the Mayo Clinic, pain clinic, reports as their rates of success for outcomes?

A. No, I have not.

Q. When you refer your patients to the pain clinic at the Mayo Clinic, why do you make those referrals?

A. Because there's nothing I can do for them, and we're trying to help the individual out in any way we can.

Q. Well, would you agree that actually sending them to the pain clinic first instead of doing surgery on them is a more conservative approach to treating their pain syndrome?

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A. If they have banding in the vagina where I can actually palpate it, I touch it and the woman literally screams, then I don't believe any physical therapy is going to be resolving that. If they have diffuse pelvic discomfort with movement, doing anything, then, by all means, you're right, I send them to the pain clinic, if they can get in.

Q. If they have banding in the vagina, you've seen it reported in the literature that in many cases that can be successfully treated by releasing the band; correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Yeah. Yeah. That's why I do it.

BY MR. SNELL:

Q. And that's how you treat the cases where there is banding. You attempt to go in and release that band that's in tension; correct?

A. Correct. And that is a very specific situation where on pelvic exam I

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can touch the specific area, you can feel it, it's like a rope, and other places it's not that way. And then I do that. I try and -- I cut it and resect as much of the mesh as I can to hope to reduce that tension.

Q. So when there's a band, you cut it and resect the mesh in that particular area; correct?

A. Only that particular area. Correct.

Q. You're not a doctor or surgeon who goes in and removes mesh over in another part of the vagina that's not banded and is not symptomatic upon examination; correct?

A. That is correct. If it ain't broke, I don't go over there.

Q. And in many cases you've been able to release that band and alleviate the painful response; correct?

A. Temporarily. I'd have to say that, again, I have not statistically analyzed this. I've had very good results for a week or two and the woman -- the last one I mentioned roughly three months ago

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came back and the pain is back. So it's very frustrating for everybody.

Q. You've had cases where there has been specific banding to one area of the vagina and you released that band and that has resulted in a positive outcome for the patient; correct?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: Yes. But you have to put the qualifier in there, temporarily.

BY MR. SNELL:

Q. In every case in which you've done a band release is it your testimony that in every one of those cases they have had further pain?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: No. Without really looking at the data closer, because I don't have that tabulated, I have to go on a gut feeling on it, which is not a very accurate way of looking at this problem.

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I would say some are improved and they have not come back. See, if they don't come back, I've kind of forgotten about them. So what I do is I see the ones who do come back, so they stick out in your mind more.
BY MR. SNELL:
Q. So in some of your patients who have had banding in the vagina you've been able to release that banding and it has alleviated their pain --
A. But --
Q. -- such that they have not come back to you; correct?
A. That -- I can't answer --
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I can't answer that because they have not come back to me.
BY MR. SNELL:
Q. Well, that's what I'm qualifying.
A. No. That may mean they've gone to a different doctor.
Q. All right. I've got you.
A. So that's why I can't -- I can't

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be statistically --
Q. How about this? In some of your patients who have had banding in their vagina for which you've gone in and released the band, they have come back to you and they have reported improvements; correct?
A. No.
Q. No?
A. They come back to me -- they've come back to me and said, I was good for a while and it is now back.
Q. I think I'm getting confused now.
Patient has a band.
A. Uh-huh. Yes.
Q. You decide I need to release that band. You do that procedure; correct?
A. Yes.
Q. We're together.
A. Yes.
Q. Do you ask those patients to come back for postoperative follow-up or do you just send them on their way?
A. We ask them -- well, to say to send them on their way sounds very cruel. What we do is say we have treated this --

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Q. Okay.
A. -- we have cut this. If you are -- if you have problems, you come back and see us.
Q. Okay.
A. If you're doing fine, there's no reason for you to come back and see me for me to tell you you're doing fine because my practice is set up such that I have people all over the world.
I cannot have somebody from Florida fly back for five minutes for me to say, oh, good, you're happy, go back home. Then I have an angry person on my hands. So my practice will not necessarily reflect other people's practices.
Q. I understand.
So you have -- all right. Let me see.
So after you -- you've treated patients by releasing the band in surgery; correct?
A. Yes.
Q. And you told them, if you have any problems, come back to me; correct?

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A. Correct.
Q. And you told them, if you're doing fine, you don't need to come back to me; correct?
A. Yes.
Q. And you would agree that there are patients who have not come back to you; correct?
A. Yes. That is correct.
Q. Do you expect patients to follow your recommendations?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I would hope they would follow my instructions.
BY MR. SNELL:
Q. If you told a patient they should go to the pain clinic at the Mayo Clinic, would you expect them to go?
A. Not necessarily. I have lots of instructions. Patients get overwhelmed, they're under stress, they're worried. They probably only hear a fraction of what I say. That's why I tend to write things down for them. I go over it. And there is

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always going to be a concern of communication issues.

If you have somebody who's in an intense amount of pain and crying in your office, which happens on a daily basis for me, they might not necessarily retain everything I say. Now, I'm quite cognizant of that.

Q. That's why you give them written referrals; correct?

A. That's why we -- a copy of my notes always go to them and to their doctor back home.

Q. That's why if you make a referral to the Mayo Pain Clinic, sometimes you'll have the pain clinic contact the -- contact the patient to see if they are going to follow that recommendation; correct?

A. I can't say that because the problem with our pain clinic is they can be out months. So if a patient is in my office, I put an order through for it and a patient is from a long ways away or has family, they can't make it to it. Because it's not like a same-day service. And they

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can't travel -- if you're in the Dakotas, the Dakotas are huge states. You can be 14 hours away and still be in one of the Dakotas. And you can't make that trip back.

Q. Besides the two cases of Prolift® mesh contraction that you've recalled, do you recall any others specific to Prolift®?

A. I don't recall any, no.

Q. I'm not sure if I asked this, but for prolapse-specific mesh contraction was the first case that you remember the 2009 case?

A. There were --

Q. Was that the first Prolift® prolapse cases?

A. No. There were more before then, but it's a blur. That's the 2009 one, it's just because that happened to be very significant with Kirkemo's death, which was not accurate.

MR. ANDERSON: Greatly exaggerated?

THE WITNESS: Yeah. That's right.

MR. ANDERSON: Can we take a

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break here in a couple of minutes? We've been going for an hour and a half.

MR. SNELL: Oh, yeah. Yes.

BY MR. SNELL:

Q. In the past year, can you give me an estimate as to the number of mesh contraction cases you have treated for prolapse?

A. It's difficult to ascertain. The only reason, I'm not trying to be difficult as far as answering your question, because in August, when that FDA report came out, I believe it was at -- well, whenever it was. I think it was in August.

It was in August when that FDA announcement came out about pelvic organ prolapse meshes, and then in September when I had a document with Public Citizen, Ralph Nader's group, read, the number of my consults started to rapidly rise and the telephone calls.

And so I can give you an idea of the number of telephone calls or requests for consultation per week are roughly three or four, maybe, per week. How many of those

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actually make it into my clinic is going to be in a given week probably five a week.

And that's a really tough guess because sometimes there's going to be a whole bunch and sometimes there's going to be none.

MR. SNELL: Okay. Take a break.

(Recess, 6:06-6:19 p.m.)

BY MR. SNELL:

Q. Ready to go?

A. Yes, sir.

Q. You're aware that Prolene has been used for about half a century?

A. Since 1958, as I recall.

Q. Have you used Prolene sutures in your surgeries?

A. Rarely. Yes.

Q. Do you use different types of sutures for different surgeries?

A. Yes.

Q. In the 1950s, surgical meshes for hernia repairs were introduced; correct?

A. Yes.

Q. In around the 1970s, surgical

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mesh was used to treat prolapse via the abdominal sacrocolpopexy; correct?
A. I don't know when it was started using there. And that sounds roughly the right time frame.
Q. In the 1990s, vaginal mesh was used to treat prolapse via the transvaginal route; correct?
A. Mesh, transvaginal, in the 1990s. I was unaware of that. The only ones I know about is the French group, and I don't know when they started.
Q. So you're not aware of when the French TVM group began looking at meshes to use in the TVM study?
A. No. What I know is some of their original studies and discussions, I saw one paper in I believe 2001, 2002, talking about the hypothesis or the possibility of doing this. So when they actually began, we'd have to predate that, which would be the late '90s.
Q. One of your criticisms of the Prolift® is that -- and any transvaginal mesh for pelvic organ prolapse is that it's

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placed through the vagina; correct?
A. Correct.
Q. And as you opine, the vagina is a contaminated environment.
A. Clean contaminated, which was supported by the depositions of Hinoul and Robinson and others.
Q. So it would be accurate that the vagina is a clean contaminated environment?
A. At the time of surgery it's a clean contaminated.
Q. Tell me what you mean by that.
A. That means that it -- you can prep the vagina -- it has to be -- well, let's back up. Let's go back to the contrast to say like an abdominal procedure where you can place Betadine and other substances, alcohol, those types of things, and get the bacterial count markedly down to as close to zero as possible for a time.
Orifice surgery, as we call it, whether it be mouth, ears -- maybe I shouldn't say ears, the ENT people would probably disagree with that -- vagina or rectum, bowel surgery, you can never even

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remotely get them sterile. You can just get them clean. You can decrease the bacterial count but it's still a contaminated field.
Q. For the abdomen, you can get the bacterial count down but not totally wipe it out; correct?
A. No. You can -- I've done one study as far as in artificial sphincters, that's a treatment for male incontinence, where we would have the patient with an antibiotic scrub for several days, then we'd do a ten-minute prep, and then we'd culture the skin at the time of surgery, and the bacterial count was essentially zero in most individuals.
So the bacteria will come back. And then you can also on the abdomen, especially if you're using prosthetics, put down -- gosh, what do you call it? There's a name, a plastic cover that sticks to the body that you cut into so that the skin is not exposed at all. So you can have it be a sterile environment.
Q. For the sacrocolpopexy?
A. You could do it for the

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sacrocolpopexy. I don't.
Q. Do you do it at Mayo Clinic as standard treatment, to put this plastic covering on the body?
A. No. But the hernia surgeons do it for the meshes.
Q. But for your sacrocolpopexies do you do it?
A. No.
Q. And when you do a sacral -- abdominal sacrocolpopexy, are you saying you put like Betadine and stuff on the stomach where you're going to make your incision?
A. That's correct. There's a standard prep we do, which is a ten-minute Betadine prep, followed by waiting five or six minutes, something, there's a certain waiting time that my surgical team does, that they have to let it dry. In the process, that theoretically decreases the bacterial count as much as possible.
Q. Does it reduce it all the way down to zero?
A. I have not studied it.
Q. Have you studied for how long

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that bacterial -- what do you call it, Doctor, where it brings the bacterial count down? Bacterial reduction?
A. Well, bacterial count.
Q. Bacterial count reduction?
A. I have --
Q. Let me just get the question because I just want to make sure I'm not using terminology that's crazy.
Do you know for how long with the Betadine prep that you've identified that is effective in reducing the bacterial count?
A. All I can correlate with that is studies that I've done with the artificial sphincter, which is roughly a 45-minute to hour-long case, we compare the culture at the beginning and the end. There are studies out there specifically in ortho, in ortho hip services, where they would culture the skin repeatedly. I don't know that data, though.
Q. Do you know data, though, for prolapse surgery like the sacrocolpopexy, for how long the bacterial count is reduced?

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A. No, I do not.
Q. And your sacrocolpopexies take more than 45 minutes; correct?
A. Yes.
Q. They take more than 60 minutes; correct?
A. Yes.
Q. Some of your sacrocolpopexies take more than three hours; correct?
A. The open sacrocolpopexies? They may have. I don't recall them taking that long.
Q. There's a risk of infection with the robotic laparoscopic sacrocolpopexy as well; correct?
A. It is a very, very small. In our series we have never had one because the mesh is taken out of the box and immediately put through the ports, never has any contact with the skin, has only sterile gloves on it, and it's put inside the patient. So unless there's any contamination from a bowel injury, which we've never had, the mesh never has contact with bacteria.
Q. Have you done any studies or

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culturing of the mesh which shows that it has no bacteria on it at the time when you place it in your robotic laparoscopic sacrocolpopexy?
A. No.
Q. The ports you make into the lady's abdomen for the robotic laparoscopic sacrocolpopexy, those ports exist from the outside skin down into the peritoneal cavity?
A. Correct.
Q. And how do you prep those ports?
A. That's with the standard Betadine prep at the beginning of the case.
Q. And so is it fair to say you do not know how much of the bacterial count is reduced for your robotic laparoscopic sacrocolpopexies two hours into the procedure?
A. There's no way to prove a hypothesis that it is still at a low level.
Q. What studies, if any, do you rely upon that show a higher rate of systemic infection with Prolift® as opposed to other prolapse surgeries?

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A. Your question as asked, I am unaware of any higher incidence of systemic infections.
Q. Next question: What studies, if any, do you rely upon which show a statistically significantly higher rate of infection for Prolift® versus other forms of prolapse surgery?
A. I'll go to my Exhibit B. I have a section on infection; however, briefly, Number 53, de Tayrac, Letouzey --
Q. Let me just get to you. I'm sorry.
A. De Tayrac, Letouzey, "Basic Science and Clinical Aspects of Mesh Infection in Pelvic Floor Reconstruction."
Q. Oh. Page 53.
A. Oh, I'm sorry. I'm sorry.
Q. I was looking at Reference 53.
A. Exhibit B, I believe. Yeah, Exhibit B.
MR. ANDERSON: Reference 53, if you look in the back.
THE WITNESS: Oh, I'm sorry.
MR. ANDERSON: Well, what do

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you have? I say look at the back.
THE WITNESS: The Exhibit B, the reference material.
MR. SNELL: Okay.
THE WITNESS: Number 53. I'm sorry.
MR. SNELL: I don't know if I have it. Maybe I do have it.
BY MR. SNELL:
Q. Is this the materials list that was served in connection with your June 15th, 2012, report, Doctor?
A. Correct.
Q. I'm having trouble putting my hands on it.
A. I can actually show you.
Q. I don't want you to show me anything that Mr. Anderson secretly marked on there.
A. No, there's nothing marked.
Number 53 -- let's go back to what the question was.
Q. The question was --
MR. SNELL: Actually, Madam Court Reporter, can you read it back to the

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doctor?
(The court reporter read back the requested portion of the record.)
MR. SNELL: That was actually not the question I wanted.
THE WITNESS: Start over.
MR. SNELL: Now that I hear it.
BY MR. SNELL:
Q. What clinical studies in humans do you rely upon which show a statistically significant higher rate of infection with Prolift® versus other prolapse surgeries?
A. Well, I have to go with that Number 53 there.
Q. Number 53?
A. De Tayrac, talking about infections in the pelvic reconstructions. And you'd have to then compare it to other standard procedures out there.
We could use Withagen's as one, that randomized, control, because infections in the traditional repair are very uncommon because you're not putting a foreign body in. Any surgery with a foreign body is

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going to be increasing the risk, whether it be in eye, hip, whatever. And so that de Tayrac one is one that I think was a very eloquently written paper on infection in the meshes.
Q. That's not a clinical study; correct?
A. Then Withagen.
Q. And it's your -- in Withagen was there an increased rate of abscess with Prolift® versus the traditional arm?
A. Let's -- well, let's get the Withagen paper out and we'll go over it.
Q. I'll get that. We'll go over it tomorrow. Is that fair? I don't have it on me right here. I have it out in my car, but I have to make a copy. So Withagen.
A. That's fine.
But you're limiting it to abscess. Multiple depositions I've read, they keep talking about abscess, abscess, abscess. Those are pyogenic bacteria. Not all bacteria are pyogenic. Candida albicans is not a pyogenic infection. Pyogenic is what forms pus.

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The one patient I talk about that had an infection after the mesh, okay, she had a diffuse cellulitis. It was a Strep. infection. So if I relied on abscess and I said, oh, no abscess, you're not infected, that's incorrect.
Q. So other than the Withagen paper, you've mentioned a bacteria, you say Candida albicans?
A. Candida albicans. It's a fungal infection. A fungus. Excuse me. Yeah, it's a fungus located in the vagina.
Q. Is it pathogenic such that it causes complications?
A. No. It's a normal -- part of the normal flora. And there are papers in my supplement referring to the normal bio -- excuse me -- the normal flora of the vagina, so that the vagina is -- has a large number of multiple different types of bacteria that are present within it.
Q. Some of which are pathogenic, some of which are non-pathogenic; correct?
A. No.
Q. No?

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A. No. I mean, just because -- there's bacteria on your skin. It's not pathogenic until you cut it and it gets in there. Okay. It's just there. It's a colonization is the best way to say it.

There are billions, literally, in the colon. It's not a problem unless you perforate your colon. So it has to be -- you have to look in that frame of reference.

Specifically in the vagina, which the vagina is unique, is the presence of the Candida albicans and the other variants of the fungi.

Q. So if the Candida albicans gets on a mesh during transvaginal placement, what's the result, if any, from an infection standpoint?

A. That would be a great one for the Ethicon to have studied. And I saw nothing in their documentations, no deposition of anybody ever considering that.

Everybody knows women can get yeast infections because why? Candida albicans. But I never saw anybody take the time to think, oh, no, what happens if this

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gets attached to the mesh put inside the body. It can be devastating, potentially.

Q. Have you ever done any studies on Candida albicans?

A. No.

Q. Besides the Withagen study, are you aware of any other studies upon which you rely that show, clinical studies, that show a statistically significant increased risk of infection with Prolift® versus some other prolapse surgery?

A. Iglesia.

Q. It's your opinion that there were more infections in Iglesia than -- in the Prolift® arm than the native repair arm?

A. I have to look at the -- infection of a mesh can manifest itself in multiple different ways, which one of the own TVM surgeons talk about that possibly infection can increase your risk for erosion. So in the Inglesia study that had a significant amount of erosions, which ultimately prompted them to stop the study. Correlating that with the TVM de Tayrac, you could theorize then that possibly that

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infection led to their erosions, at least in part.

Q. I don't really want theory. I want what you're going to testify to to a reasonable degree of medical certainty --

A. I just --

Q. -- at the time of trial.

Are you going to say that the 15 percent erosions in Iglesia, all of those patients had concomitant infection?

A. That's not what I said.

Q. Do you believe all 15 percent -- do you believe all of the erosion cases in the Iglesia study had concomitant infection?

A. That's not what I said.

Q. I'm asking what you believe. I know that's not what you've said or that's not how we're interpreting each other. I'm asking you if you believe that.

A. Well, I --

Q. If you're going to come into court at trial and say, those people who had mesh exposures in the Prolift® arm in the Iglesia study all had infections.

A. Here's what -- exactly what I

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will say --

Q. Okay.

A. -- with scientific data to back me up, that a TVM surgeon, highly experienced in Prolift® and Gynemesh®, states in a paper that erosion can possibly be caused by infection.

I will then say that the vagina is a clean contaminated environment. It cannot -- physically impossible to be sterilized. So, therefore, every time there is an erosion -- excuse me -- extrusion or possibly erosion, contamination and infection can specifically be playing a significant role. That's what I'll say on the stand, which, according to Hinoul's, Hinoul --

MR. ANDERSON: Hinoul.

THE WITNESS: -- Hinoul's deposition, he stated he knew, Ethicon knew, every possible complication prior to launch; therefore, they knew this was a risk.

BY MR. SNELL:

Q. They knew that mesh exposure was a risk? Is that what you're going to come

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in and say?
A. Mesh exposure is a risk? Yes, they knew that.
Q. They knew that infection was a potential risk. Is that what you're going to come in and say?
A. Yes.
Q. Who's this TVM surgeon you're referring to?
A. De Tayrac. He's Number 53 there.
Q. So you believe that de Tayrac was one of the TVM group.
A. No. I believe I've seen his name in some of the French studies on Gynemesh®. I don't know -- I have not looked at, at least I can't recall, all of the specific TVM surgeons.
Q. And because this surgeon said that erosion can possibly be caused by infection, you will extrapolate that statement by a single physician to your opinion that every time there is an erosion, contamination and infection can specifically be playing a significant role.
MR. ANDERSON: Objection.

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Misstates prior testimony.
BY MR. SNELL:
Q. Is that correct?
MR. ANDERSON: Objection. Misstates prior testimony.
THE WITNESS: Well, no. We can go to Number 69 on there.
MR. SNELL: Okay.
THE WITNESS: Is that --
BY MR. SNELL:
Q. That's Falagas?
A. Falagas.
There's Number 121, which is M-A-M-Y. All of which are stating and theorizing the possibilities of infections and the consequences of infections, which erosions are.
Q. So 69, Falagas, and what was the next one?
A. 121, I believe, M-A-M-Y.
And the other one would be general surgery in my supplemental report. Her name -- I think it's a her. C-H-O-I. That is general surgery looking at clean contaminated wounds in general surgery

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markedly increasing the risk of complications.
So I'm -- I'm talking -- you asked me specifically, as I told you, a few. We could go point by point through my report for more.
Q. I'm not sure if we're communicating.
What I'm actually looking for is clinical data where there were higher rates of infection with the Prolift® versus some other prolapse procedure, not theory, not what some doctor said in France or what some surgeon said based upon bench research. I'm talking about clinical data from a study, retrospective, prospective, randomized, controlled trial. That's what I'm looking for.
A. Okay.
MR. ANDERSON: Objection.
If that's how you're defining clinical data, that's the first time that you've done that. Before, you just said clinical data.
MR. SNELL: I thought I said

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clinical study data, clinical trial data.
MR. ANDERSON: Well, you didn't. So that does change the question. Is that your question?
MR. SNELL: Yes.
MR. ANDERSON: How many -- clinical trial data regarding this statistically significant increase in infection with Prolift® versus a non-surgical -- non-transvaginal mesh repair.
MR. SNELL: Non-traditional.
MR. ANDERSON: Okay. Okay.
MR. SNELL: Let me say it. I mean, you were pretty good there.
MR. ANDERSON: I'm just trying to make sure I understand it.
MR. SNELL: No. You were pretty good there, actually.
MR. ANDERSON: I think it's really good myself but, you know.
BY MR. SNELL:
Q. So are you aware of clinical trial data that shows a statistically significant increased risk with Prolift®

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versus some other type of prolapse repair surgery that you relied upon, with the caveat that when I say clinical trial data, I mean data in humans from retrospective, prospective, clinical studies and/or randomized, controlled trials.

MR. ANDERSON: Objection. Asked and answered to some extent of the ones he's already mentioned.

Go ahead.

THE WITNESS: I am physically incapable of thinking into a putting up all these borders and definition of data.

If you exclude volumes of data, say, oh, no, we're not talking about de Tayrac, Letouzey, not Letouzey, the other ones, just a specific clinical study that looked only at infection, by that definition, no, I cannot. But I think that is academically, intellectually incompetent and wrong. You have to look at the totality of knowledge and not narrow it.

(Discussion off the record.)

BY MR. SNELL:

Q. Doctor, some of the articles you

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cite to in your expert report and materials list involve the abdominal sacrocolpopexy; correct?

A. I'd have to look back. I don't -- I don't -- I'm sure I would have included it in there because I'm looking at all of it but I don't recall off the top of my head.

Q. You would agree, Doctor, that in clinical studies looking at sacrocolpopexy -- and I'm talking about the open abdominal sacrocolpopexy and laparoscopic sacrocolpopexy. Are we together?

A. Yes. Is that including robotics?

Q. I'm setting aside your robotics.

A. Laparoscopic. Okay.

Q. So you would agree that in studies involving open abdominal and laparoscopic sacrocolpopexy, as I've defined it, some of those patients also have hysterectomies at the time of the surgery; correct?

A. That is correct.

Q. And you would agree that the vagina would be exposed to these same

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bacterium -- strike that.

You would agree that the abdomen and the peritoneal cavity would be exposed to these same bacteria from the vagina if a hysterectomy is done at the time of a sacrocolpopexy; correct?

A. Then you have the ability to wash it out.

Q. Let's just answer my question first and then we can get into washing.

A. Yes.

Q. When a hysterectomy is done at the time of an abdominal sacrocolpopexy, the bacteria from the vagina can get into the peritoneal cavity; correct?

A. Yes.

Q. Any time there is a fresh incision to the cuff where the uterus was at the time of an abdominal sacrocolpopexy, those vaginal organisms can get into the abdominal cavity; correct?

A. Yes.

Q. If you are doing an abdominal sacrocolpopexy and a suture is passed through the full thickness of the vaginal

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wall, the abdominal cavity is, therefore, exposed to these same vaginal bacteria; correct?

A. No. The suture is exposed, the part that's inside the vagina. I wouldn't say the abdomen is exposed.

Q. Is it your belief that when the suture is withdrawn or passed through, the bacteria cannot get through that same space?

A. It could.

Q. How large are bacteria?

A. Tiny.

Q. One, two microns.

A. I don't know. They're tiny.

Q. They're smaller than the gauge of the needle that you use when you suture; correct?

A. I don't know. Well, I don't know how big the gauge -- I understand they are very, very small.

Q. Now, you mentioned you can wash the abdomen out if you do a hysterectomy at the time of a sacrocolpopexy; is that correct?

A. Yeah. I don't do hysterectomies

so I'm going to be theorizing on what other people's works are. Remember, if a woman needs a hysterectomy, that goes to my gynecology colleagues.

Q. Okay.

A. But what I mean by washing it out is in my OR specifically there is standard practice of constantly washing out any wound. The solution to pollution is dilution. Okay. So we will use several liters of antibiotic solution multiple times throughout the case and at times actually use Betadine.

Q. And what scientific literature or data are you aware of that shows that if you do that, what you just said, in a case where there's a concomitant hysterectomy done that the bacteria from the vagina would come -- be rendered either impotent or are physically removed out of the entire abdomen?

A. I rely on data outside the hysterectomy group for that, for that conclusion.

Q. What data is this?

A. Penile prostheses infections by Dr. John Mulcahy at the University of Indiana.

Infected penile prosthetics, a prosthetic, if it comes infected, there's a protocol for washing it out. You can actually wash out the bacteria under high pressure and put a penile prosthesis in and then the prosthesis has a high chance of survival. So that is in a worst-case scenario.

Q. But this clean contaminated vagina area has different bacteria than this penile prosthesis procedure; correct?

A. The only one that would probably be potentially different would be the Candida.

Q. Do you know the difference in the amount of bacteria released from performing a hysterectomy when the uterus is cut out and removed as compared to the amount of bacterium released when there is this penile prosthesis?

A. No.

Q. So is it correct, Doctor, that

you are essentially extrapolating some data from penile prostheses into the sacrocolpopexy with concomitant hysterectomy situation?

A. I'm extrapolating infection data.

MR. SNELL: What time is it, gentlemen?

MR. ANDERSON: 7:00.

MR. SNELL: Let's shut down.

(Whereupon the deposition adjourned at 6:56 p.m.)

TESTIMONY ADJOURNED

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was not requested before completion of the deposition that the witness, DANIEL STEVEN ELLIOTT, M.D., have the opportunity to read and sign the deposition transcript.

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LAWYER'S NOTES

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